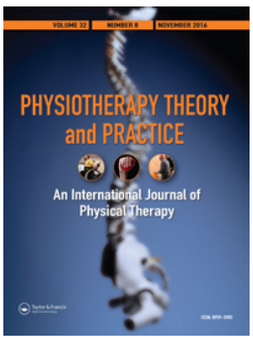

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DESCRIPTIVE REPORT

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Funding is related to the quality, conduct, and reporting of trial reports in musculoskeletal physical therapy: A survey of 210 published trials

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ABSTRACT

Background: The relationship between trial funding and methodological quality, the conduct and reporting of trials has been investigated in several medical disciplines, but remains unclear in musculoskeletal physical therapy trials. The aim of this study was to determine the association between funding and research team composition, sample size, quality, and journal impact factor of randomized controlled trial reports in musculoskeletal physical therapy. ***Methods***: A survey of 210 trial reports in musculoskeletal physical therapy, which were randomly selected from those published in 2011–2013 and indexed on the Physiotherapy Evidence Database (PEDro), is performed. Total PEDro score and citation details of the trial reports were downloaded from PEDro. Pairs of assessors independently extracted information about funding, sample size, and composition of the research team. Journal impact factor was downloaded by one reviewer. ***Results***: Trial funding was associated with having multiple departments in the research team (odds ratio: 1.89, 95% confidence interval: 1.03–3.49), larger sample size (median: n = 72 versus n = 50), higher quality (mean PEDro score: 6.06 versus 5.11), and publication in journals with higher impact factors (median: 2.12 versus 1.78). ***Conclusion***: Trial funding was positively associated with having multiple departments represented in the research team, larger sample size, higher quality, and publication in higher impact factor journals.

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Funding; methodological quality; musculoskeletal physiotherapy

Introduction

Published trials are often involved in a complex paradox; the greater the effect of the intervention, the lower the methodological quality of the trial seems to be (Moher et al, 1998; Schulz, Chalmers, Hayes, and Altman, 1995; Wood et al, 2008; Yank, Rennie, and Bero, 2007). The relationship between trial funding and various aspects related to the methodological quality has been investigated in several medical disciplines and shows varying results (Djulbegovic et al, 2000; Jefferson et al, 2009; Reed et al, 2007). In many areas of medical research, funding appears to be related to a positive outcome in favor of the pro-industry findings (Bhandari et al, 2004; Djulbegovic et al, 2000; Kelly et al, 2006; Lexchin, Bero, Djulbegovic, and Clark, 2003; Yaphe, Edman, Knishkowy, and Herman, 2001). While trials that receive funding from research councils are more likely to have better quality because the peer review process facilitates the use of stronger research methodology and multi-institutional collaborations (Reed, Kern, Levine, and Wright, 2005). Therefore, methodological quality is an important aspect to consider while assessing and using the results of a trial.

In physical therapy trials, the influence of funding on methodological quality and other aspects of trial conduct and reporting remains unclear. The association between funding and quality has only been evaluated for cardiothoracic physical therapy. In trial reports for cardiothoracic physical therapy, funding was associated with a 0.14-point increase in total Physiotherapy Evidence Database (PEDro) score (0–10) (Geha et al, 2013). This small association might be explained by the possible limited role of the industry in physical therapy research compared to medical or surgical research. The role of funding may be dependent on the physical therapy sub-discipline. In this study, we focus on musculoskeletal physical therapy. Our choice was motivated by the fact that musculoskeletal physical therapy is a relevant domain in physical therapy, in which the association between funding and quality is unknown. Furthermore, this subdiscipline has the largest number of trial reports indexed on PEDro including many

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recent publications (Moseley, Elkins, Janer-Duncan, and Hush, 2014).

Funding may increase the methodological quality of musculoskeletal physical therapy trials in several ways. The funds would allow an investigator to pay for a central randomization service and so achieve concealed allocation, to employ a statistician to plan the analyses and so implement intention-to-treat analysis, or to employ staff to provide better follow-up in order to lower the drop-out rate or permit blinded outcome assessment. Funding could also influence other aspects of the conduct and reporting of musculoskeletal trials, including implementing in on more than one site (i.e., multicenter), thereby involving investigators from more departments and increasing the sample size recruited. Given the argument that trials which receive funding probably have more investigators (i.e., larger research teams), larger samples sizes, and a better methodological quality, it is likely that the trial reports will probably be published in journals with a high impact factor. Therefore, funding and journal impact factor might also be related in physical therapy trials.

The aim of this survey was to evaluate if funding is associated with research team composition, sample size, quality, and journal impact factor of reports of randomized controlled trials in musculoskeletal physical therapy.

Methods

Data sources and study selection

PEDro was selected as data source because it is the most complete index of reports of randomized controlled trials in the field of physical therapy (Centre for Evidence-Based Physiotherapy, 2014). All trial reports in PEDro are coded for: the subdiscipline of physical therapy (e.g., cardiothoracics; musculoskeletal; or pediatrics); therapy (e.g., acupuncture; stretching; mobilization; manipulation; or massage); problem (e.g., frailty; pain; muscle shortening; or reduced joint compliance); and body part (e.g., head or neck; upper arm; shoulder or shoulder girdle; lumbar spine; sacro-iliac joint; or pelvis). Up to three codes in each category can be applied to each trial report. Furthermore, all trial reports in PEDro are assessed for methodological quality using the 11-item PEDro score (Centre for Evidence-Based Physiotherapy, 2014; Michaleff et al, 2011; Moseley et al, 2009). This score is easily accessible for physical therapists and therefore a practical tool to inform them about the quality of trial reports. Citation details of all trial reports coded as "musculoskeletal" for sub-discipline, written in English and published in 2011–2013 were downloaded from the May 4, 2014 update of PEDro. A random sample of 20% of the total number of trial reports for each year (2011–2013) was selected using Microsoft Excel software. By selecting these trial reports a manageable sample was created.

Independent variable: Funding

Trial funding was the independent variable to which the association to the methodological quality parameters was assessed. Trial funding was classified as "funded" (i.e., industry or private company, professional organization, charity, research council, national government, international government, or university); "unfunded"; "unclear"; or "other." Because of a lack in variation in funding source, the variable was dichotomized to "0" if the trial did not receive funding or the funding status was unclear and "1" if the trial received funding.

Dependent variables: Research team composition, sample size, quality, and journal impact factor

Composition of the research team was assessed by the number of departments included in a research team. This variable was dichotomized into "0" if only one department was included in a research team and "1" if two or more departments were included in a research team. Trials in which the number of departments remained unclear were coded as "0" (as if all authors were from one department). This is the most conservative assumption, because the hypothesis was that multiple departments included in a research team would be associated with higher methodological quality. Sample sizes were directly extracted from the trial reports and analyzed as a continuous variable. The assessment of methodological quality was based on the total PEDro score. The total PEDro score has been shown to be a valid and reliable measure of methodological quality of trial reports evaluating physical therapy treatments (de Morton, 2009; Macedo et al, 2010; Maher et al, 2003). The 11-items of the PEDro score are: 1) eligibility criteria and source specified; 2) random allocation; 3) concealed allocation; 4) baseline comparability; 5) blinding of subjects; 6) blinding of therapists; 7) blinding of assessors; 8) more than 85% follow-up; 9) intention-to-treat analysis; 10) reporting of between-group statistical comparisons; and 11) reporting of point measures and measures of variability. The last 10 items were used to calculate the total PEDro score by summing the number of items fulfilled; the first item was not used because it relates to generalizability rather than methodological quality. The total PEDro score therefore ranges from 0 to 10 in which higher scores indicate

higher methodological quality. The 2012 impact factor for the journal that published a report was downloaded from Web of Knowledge (Thompson, 2009).

Language of publication, time since publication and subdiscipline of physical therapy have all been shown in previous research to be associated with trial quality (Geha et al, 2013; Moseley, Elkins, Janer-Duncan, and Hush, 2014; Moseley et al, 2011). These variables were not included as methodological quality parameters because only trial reports in musculoskeletal physical therapy published in the last three years in English were included in this study.

Data extraction

The citation (including the year of publication and journal name), total PEDro score and codes for subdiscipline of physical therapy, problem being treated, body part being treated, and therapy being evaluated were downloaded from the May 4, 2014 update of PEDro (Centre for Evidence-Based Physiotherapy, 2014). Two assessors, independently extracted data from the full text of the included trial reports for funding, research team composition, and sample size. Any disagreements were resolved by discussion or, if necessary, arbitration by a third reviewer. A training session was organized before performing the data extraction to ensure a common interpretation of the operationalization of the variables. If the full-text report did not contain sufficient data to extract the variables, the following trial registrations were consulted: ClinicalTrials.gov; International Standard Randomised Controlled Trial Number Register; Australian New Zealand Clinical Trials Registry; and the national register of the country of origin of each author. If the variables could not be determined from the full-text report and trial registration, an e-mail was sent to the corresponding author to obtain the missing data. A reminder e-mail was sent one week later, if necessary. The journal impact factor data were downloaded by one reviewer.

Data analysis

Proportions and absolute numbers were used to summarize the descriptive characteristics of all trial reports. Percentages of included trial reports with each code for therapy, body part, and problem were described. Mean and standard deviation (SD) were calculated for data that followed a normal distribution or median, and interquartile range (IQR) for data that did not follow a normal distribution.

Dependent variables were: research team composition (0 = mono-departmental or unclear, 1 = multi-departmental); sample size (continuous); quality (total PEDro score (continuous, 0–10)); and journal impact factor (continuous). The independent variable was "funding" (0 = no/unclear and 1 = yes.

Two types of analyses were used: 1) univariate regression analyses were performed to assess the association between funding and research team composition (logistic regression) and the association between funding and quality (linear regression) and 2) Mann–Whitney *U*-tests were performed to assess the associations between funding and sample size; and funding and journal impact factor, because of the skewedness of two dependent variables. This test assumes no difference in sample size and journal impact factor between the funded trials and the trials which were unfunded or where funding was unclear. *P*-values lower than 0.05 were considered statistically significant. All analyses were carried out using SPSS version 21.

Sensitivity analysis

Sensitivity analyses were performed to assess the assumption that trials in which funding was unclear was analyzed as unfunded. The trials of which funding was unclear were excluded from the analysis.

Results

Characteristics of the trial reports

On May 4, 2014, PEDro indexed 22,052 trial reports, 5089 in English, coded as musculoskeletal and with confirmed PEDro scale ratings. Random sampling of reports published in 2011–2013 resulted in 210 included trial reports. The selection procedure is described in Figure 1. Three trial reports were excluded because the report: 1) was a duplicate publication of another included trial (Higgins, Cameron, and Climstein, 2013); 2) did not describe a randomized controlled trial (which has subsequently been removed from PEDro) (Sweeting, Whitty, Scuffham, and Yelland, 2011); or 3) only covered immediate response to patient preferences using a repeated measures design (Cè et al, 2013).

Disagreement in data extraction between the assessors was 15% (231 of 1491 items). Most disagreements related to rating composition of the research team, because the departments were not always described clearly. For two items, the decision was made by a third reviewer; all other disagreements were resolved by consensus discussions between the two independent assessors.

The health problem codes most frequently used for the included trials were: pain (83.8%); reduced exercise tolerance (15.2%); and muscle shortening, reduced joint compliance (12.4%). The most frequently used body

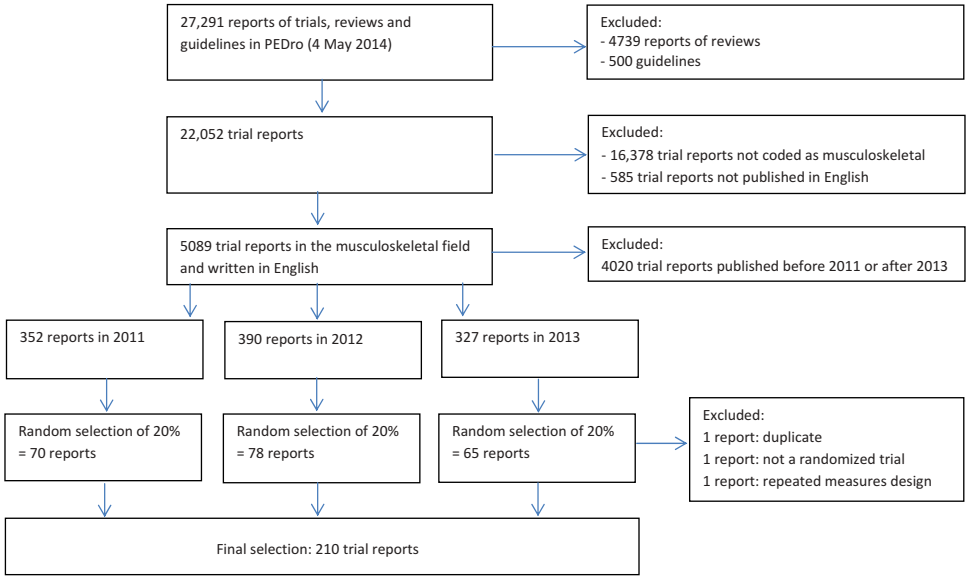

Figure 1. Study flow diagram.

part codes were: lumbar spine, sacroiliac joint or pelvis (22.8%); lower leg or knee (19.5%); and head or neck (15.2%). The most frequently used therapy codes were: stretching, mobilization, manipulation, and massage (33.3%); strength training (28.1%); and electrotherapy, heat, and cold (20.0%). A full list of the codes applied to the included trials is shown in Table 1.

Independent variable: Funding

The majority of included trials reported being funded (130/210, 61.9%). In 32.0% of the reports the source of funding was stated in the full text, with the remaining 29.9% of trials being categorized based on documentation in trial registers or by correspondence with the authors. Unfunded trials comprised those where the full-text report made no mention of funding and where trial registration or correspondence with authors did not clarify the funding status (80/210, 38.1%).

Dependent variables: Research team composition, sample size, quality, and journal impact factor

Most trials were published by investigators from more than one department (71.9%). Of the multidepartmental research teams, 84% consisted of authors from more than two departments. The sample size of the included trial reports ranged from 9 to 1409 participants (median = 57, IQR = 34; 119). The total PEDro score was normally distributed and was similar to all English-language reports of musculoskeletal physical therapy trials published in 2011–2013 (mean difference = 0.01; 95% confidence interval (CI) = −0.22; 0.24). The total PEDro score of the included trial reports ranged from 2 to 10, with a mean of 5.70 (SD 1.72). Journal impact factor ranged from 0.00 to 51.60 (median = 1.88,

Table 1. The codes for problem, body part, and therapy for the included trial reports (N = 210).

Problem (N (%))	Body part (N (%))	Therapy (N (%))
Pain: 176 (83.8%)	Lumbar spine, sacroiliac joint or pelvis: 48 (22.8%)	Stretching, mobilization, manipulation, massage: 70 (33.3%)
Reduced exercise tolerance: 32 (15.2%)	Lower leg or knee: 41 (19.5%)	Strength training: 59 (28.1%)
Muscle shortening, reduced joint compliance: 26 (12.4%)	Head or neck: 32 (15.2%)	Electrotherapy, heat, cold: 42 (20.0%)
Muscle weakness: 21 (10.0%)	Upper arm, shoulder or shoulder girdle: 29 (13.8%)	Education: 33 (15.7%)
Motor incoordination: 7 (3.3%)	Thigh or hip: 14 (6.7%)	Behavior modification: 29 (13.8%)
Reduced work tolerance: 6 (2.8%)	Foot or ankle: 13 (6.1%)	Skill training: 25 (11.9%)
Frailty: 2 (0.9%)	Hand or wrist: 14 (5.7%)	Fitness training: 23 (10.9%)
Difficulty with sputum clearance: 0 (0.0%)	Forearm or elbow: 7 (3.3%)	Acupuncture: 20 (9.5%)
Incontinence: 0 (0.0%)	Thoracic spine: 3 (1.4%)	Orthoses, taping, splinting: 15 (7.1%)
Impaired ventilation: 0 (0.0%)	Perineum or genito-urinary system: 2 (0.9%)	Hydrotherapy, balneotherapy: 6 (2.8%)
Edema: 0 (0.0%)	Chest: 0 (0.0%)	Health promotion: 6 (2.8%)
Skin lesion: 0 (0.0%)	No appropriate value in this field: 43 (20.4%)	Neurodevelopmental therapy, neurofacilitation: 2 (1.0%)
No appropriate value in this field: 16 (7.6%)		Respiratory therapy: 0 (0.0%)
		No appropriate value in this field: 9 (4.2%)

Note: Each trial report can have up to three problems, body part and therapy codes so the percentages in each column do not add up to 100%.

IQR = 1.33; 2.57), with 80.0% having a journal impact factor under 3.00 and 12.30% of journals not having an impact factor. Detailed information about the distribution of all variables is shown in Table 2.

Association between funding and research team composition, sample size, quality, and journal impact factor

For the 130 funded trials, the median sample size was 72, the mean quality based on the total PEDro score was 6.06, and median journal impact factor was 2.12. These variables were all higher compared to 80 trials which were unfunded or where funding was unclear, in which the median sample size was 50, mean quality score was 5.11, and the median journal impact factor 1.78. In funded trials, 76.9% of the research teams consisted of investigators from more than one department compared to 63.8% in the trials which were unfunded or where funding was unclear. Detailed information about all variables is shown in Table 2.

Table 2. Characteristics of the independent variables (predictors) of a sample of musculoskeletal physical therapy trial reports.

	All trials	Funded trials	Unclear or unfunded trials
Research team composition			
One department involved (*N* (%))	59 (28.1%)	30 (23.1%)	29 (36.2%)
Two or more departments involved (*N* (%))	151 (71.9%)	100 (76.9%)	51 (63.8%)
Sample size			
N	210	130	80
Median (IQR)	57.00 (34–115)	72.00 (36–157)	50.00 (30–75)
Quality based on total PEDro score			
N	210	130	80
Mean (SD)	5.70 (1.72)	6.06 (1.59)	5.11 (1.78)
Journal impact factor			
N	210	130	80
Median (IQR)	1.88 (1.33–2.57)	2.12 (1.40–3.11)	1.78 (0.98–2.21)

SD = standard deviation; IQR = interquartile range.

A positive association is shown between trial funding and research team composition with investigators from more than one department (odds ratio (OR) = 1.89, 95% CI = 1.03; 3.49) (Table 3). Mann–Whitney *U*-test shows that the median sample size for trials that are funded is significantly higher than that of the trials which were unfunded or where funding was unclear (median: $n = 72$ versus $n = 50$; $P = 0.005$). Also a positive association was found between funding and the methodological quality of the trial report based on total PEDro score ($B = 0.95$, $P < 0.001$, $R^2 = 0.072$). In other words, trials which received funding have an almost 1-point higher total PEDro score compared to trial reports which were unfunded or where funding was unclear. Mann–Whitney *U*-test also shows that trials which are funded are published in journals which have a significantly higher journal impact factor compared to trials which were unfunded or where funding was unclear (median = 2.12 versus 1.78; $P = 0.008$).

Sensitivity analysis

From the 210 trials, 130 trials (61.9%) received funding, 44 trials (21.0%) were unfunded and for the remaining 36 trials (17.1%) funding was unclear. In all previous analyses, the trials in which funding was unclear were assumed to be unfunded. To assess the influence of this decision, a sensitivity analysis was performed in which trials for which funding was unclear were excluded from the analysis. The total number of trials in this sensitivity analysis was 174, because in 36 of the 210 trial reports the funding status was unclear. There is no change in interpretation for the association between funding and sample size plus funding and quality. The associations between funding and research team composition plus funding and journal impact factor were no longer statistically significant (Table 3).

Table 3. Analysis of the relation between funding and research team composition, sample size, quality (based on total PEDro score), and journal impact factor.

Is there a relationship between:	Main analysis (*N* = 210)	Interpretation main analysis	Sensitivity analysis (*N* = 174)	Interpretation sensitivity analysis
Funding and research team composition?	OR = 1.89* 95% CI = 1.03–3.49 *P* = 0.040	Positive association between funded trials and having researchers from multiple departments involved in the trial.	OR = 1.25 95% CI = 0.57–2.72 *P* = 0.574	Change in interpretation: no significant difference
Funding and sample size?	*Z* = 2.807** *P* = 0.005	The median of the sample size is 22 points higher in trials that are funded.	*Z* = 2.260* *P* = 0.024	No change in interpretation
Funding and quality (based on total PEDro score)?	*B* = 0.95*** 95% CI = 0.48–1.42 R^2 = 0.072 *P* < 0.001	Mean quality is based on PEDro is 5.70 and is 0.95 points higher in PEDro score in trials that are funded.	*B* = 0.79** 95% CI = 0.23–1.34 R^2 = 0.044 *P* = 0.006	No change in interpretation
Funding and journal impact factor?	*Z* = 2.66** *P* = 0.008	The median journal impact factor is 0.34 points higher in trials that are funded.	*Z* = 1.91 *P* = 0.056	Change in interpretation: no significant difference

* = <0.05; ** = <0.01; *** = <0.001.

Discussion

The primary aim of this study was to evaluate if funding was associated with research team composition, sample size, quality, and journal impact factor of randomized controlled trial reports in musculoskeletal physical therapy. The main driver for this study was to assess if trials in musculoskeletal physical therapy performed without funding are associated with different quality, conduct, and reporting features compared to trials that do receive funding. Even though obtaining funding for physical therapy trials is highly competitive, this study shows the important relationship between funding and trial quality, conduct, and reporting parameters.

Positive associations were found between receiving any type of research funding and all quality, conduct, and reporting parameters. Trial funding is associated with having researchers from more departments in the research team (OR 1.89, 95% CI: 1.03; 3.49), having larger sample sizes (median = 72 versus 50), higher quality (mean = 6.06 versus 5.11), and publication in journals with higher impact factors (median = 2.12 versus 1.78) in trials which received funding in comparison to trials in which funding is unclear or did not receive funding. However, the associations between funding and the research team composition plus funding and journal impact factor were no longer statistically significant when the trials for which funding was unclear were excluded from the analysis. One explanation might be that excluding these trials reduced the number of studies in our sample and reduced the statistical power. Furthermore, the imprecision of our measurement of research team composition (i.e., categorization as from a single department versus multiple departments) may have contributed to the nonsignificant association in the sensitivity analysis.

Our study is comparable to other research in physical therapy by showing the positive association between funding and total PEDro score in cardiothoracic physical therapy (Geha et al, 2013). The cardiothoracic subdiscipline has the second largest quanta of evidence indexed in PEDro and accounts for 20% of the trials (Moseley, Elkins, Janer-Duncan, and Hush, 2014). Similar results occur in other medical fields (Reed et al, 2007).

Strengths of this study are the unbiased methods used for data extraction (double extraction by independent assessors after a training session) and the use of a large random sample of trials in the field of musculoskeletal physical therapy. Of the 11 areas of physical therapy included in PEDro, musculoskeletal is the biggest, accounting for 26% of all trial reports (Moseley, Elkins, Janer-Duncan, and Hush, 2014) and we used one-fifth of the reports published in 2011–2013 in this survey. The sample is a good reflection of all recently published trials in this field.

The most important limitation of this survey is that it was impossible to assess the source of the funding, because of the incomplete information in the trial reports. Despite an extensive search in trial registries and correspondence with the authors, it was unclear if funding was received in 38.1% of the trials evaluated in our survey. Therefore, our analyses were restricted to the evaluation of funding in general, rather than specific sources of funding. In many areas of medical research, industry funding appears to be related to a positive outcome in favor of the pro-industry findings (Bhandari et al, 2004; Djulbegovic et al, 2000; Kelly et al, 2006; Lexchin, Bero, Djulbegovic, and Clark, 2003; Yaphe, Edman, Knishkowy, and Herman, 2001). Only 2.4% of the trial reports in our survey received industry funding. Based on this survey, the role of industry in musculoskeletal physical therapy trials seems to be limited. However, it needs to be taken into account that it was unclear if funding was received in over one-third of the trials evaluated in this survey. To provide more definite evidence on the role of different funding sources, there is a strong need for transparency about the funding source. Implementation of the CONSORT statement may improve reporting of randomized controlled trials (Schulz, Altman, and Moher, 2010). The second limitation was the operationalization of the variable "research team composition." We intended to document the qualifications of each of the trial authors in order to quantify research team composition, but a pilot test of the data extraction form revealed these data were rarely available. Therefore, the role of having researchers with a specific affiliation (i.e., a statistician or methodologist) in the team that could have increased the quality of the trial could not be assessed in this survey.

Recommendations for future research in this area are first validation in an independent sample of trials and the use of a more sensitive metric to quantify research team composition (possibly involving extracting the number, affiliations and countries of the authors) (Wiles, Olds, and Williams, 2010). Second, it should be noted that the overall range in trial quality and journal impact factor in this sample is small and most studies report pain as most important problem. Evaluating a broader sample of trials may enhance generalizability and make the impact of funding source more visible. Another knowledge gap in physical therapy trials is the possible discordance between the results reported in the results section of the full-text paper and in the conclusion section of the

abstract or full-text paper, and the association between funding and this discordance. Namely, it has been shown in medical trials that results are not reported consistently within the full-text reports (Yank, Rennie, and Bero, 2007) and a lack of concordance between results and conclusion sections is associated with poor methodological quality and financial ties to a drug company (Jefferson et al, 2009; Yank, Rennie, and Bero, 2007). These relationships have not been investigated in the field of physical therapy.

The published reports of funded trials typically have a higher total PEDro score. Consequently, the following pathway can be hypothesized: funding of physical therapy trials allows a multidisciplinary research team, higher sample size, a better quality and these trials are published in higher impact factor journals. Although obtaining research funding is highly competitive, based on this study, it is recommended that physical therapy researchers apply for research funding. Furthermore, making guidelines and policy decisions based upon small unfunded trials with low quality ratings might be misleading. Larger, well-performed, and funded trials can give an important contribution to evidence-based physical therapy and should therefore be emphasized in the teaching and practice of physical therapy.

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Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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