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**Reporting of rehabilitation intervention for low back pain in randomized controlled trials: is the treatment fully replicable?**

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## ABSTRACT

**Study Design.** Methodological review of randomized controlled trials (RCTs).

**Objective.** To assess the quality of reporting of rehabilitation interventions for mechanical low back pain in published RCTs.

**Summary of Background Data.** Reporting of interventions in RCTs often focused on the outcome value and failed to describe interventions adequately.

**Methods.** We systematically searched for all RCTs in Cochrane systematic reviews (SRs) on low back pain published in The Cochrane Database of Systematic Reviews until December 2013. The description of rehabilitation interventions of each RCT was evaluated independently by two of the investigators, using an ad hoc checklist of seven items. The primary outcome was the number of items reported in sufficient details to be replicable in a new RCT or in everyday practice.

**Results.** We found 11 SRs, including 220 eligible RCTs, on low back pain. Of those, 185 RCTs were included. The median publication year was 1998 (I-III quartiles, 1990-2004). The most reported items were the characteristics of participants (91.3%; 95% CI, 87.3%-95.4%), the intervention providers (81.1%; 95% CI, 75.4%-86.7%), and the intervention schedule (69.7%; 95% CI, 63%-76%). Based on the description of the intervention, less than one fifth would be replicable clinically. The proportion of trials providing all essential information about the participants and interventions increased from 14% (n= 7) in 1971-1980 to 20% (n= 75) in 2001-2010.

**Conclusions.** Despite the remarkable amount of energy spent producing RCTs in low back pain rehabilitation, the majority of RCTs failed to report sufficient information that would allow the intervention to be replicated in clinical practice. Improving the quality of intervention description is urgently needed to better transfer research into rehabilitation practices.

**Key Words:** Systematic Review, Randomized Controlled Trials, Rehabilitation, Evidence-Based Practice, Intervention Studies, Therapeutics, Low Back Pain, health care providers, Epidemiologic Methods, Data Reporting, Reproducibility of Results, Decision Making

**Level of Evidence:** 1

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## Introduction

Performing health research is costly and time-consuming; often, the results are slowly or not at all translated into clinical practice. One of the main obstacles to transferring research findings into practice is the gap in communication between those who produce research and those who use it<sup>1</sup>. The *knowledge producers* often focus on reporting the results and fail to describe the interventions adequately<sup>2</sup>. The *knowledge users*, consequently, become frustrated as the research findings are difficult to interpret and apply outside their original Randomized Controlled Trials (RCTs)<sup>3</sup>. This gap might lead to the under-use of effective treatments, the incorrect use of treatments, or the over-use of unhelpful or obsolete treatments<sup>1</sup>.

Before dissemination, therapeutic innovations require: (1) well-executed research demonstrating treatment effectiveness, and (2) a description of the treatment procedure with sufficient detail to allow its replication by health professionals in practice. Both elements require adequate reporting, defined as the extent to which a report provides information about the design, conduct, and analysis of the trial.<sup>4</sup>

A study including 80 RCTs and Systematic Reviews (SRs), which were selected by the journal Evidence-Based Medicine for their relevance and newsworthiness, showed that 51% of the articles had an 'inadequate' description of the treatment<sup>5</sup>. Another study found that 57% (29/51) of the interventions could not be replicated based on the description of the treatment as published<sup>6</sup>.

Pharmaceutical studies provided better descriptions of the treatments compared to studies on non-drug treatments, with 33% (7/21) of drug trials and 73% (22/30) of non-drug trials deemed non-replicable. Rehabilitation interventions are non-pharmacological treatments and are often not adequately reported<sup>7</sup>.

In this review, we aimed to assess the quality of the description, or equivalently reporting of rehabilitation interventions for Low Back Pain (LBP) in randomized controlled trials (RCTs) included in Cochrane SRs. Furthermore, we evaluated the relationship between the quality of reporting of rehabilitation interventions for LBP and the year of publication, presence of funding, and the continent in which the study was conducted.

## **Methods**

### **Strategy search and Eligibility criteria**

We searched the Cochrane Database for Systematic Review published from 1995 up to December 2013, using the terms ‘back pain’ and ‘rehabilitation’. We focused on Cochrane SRs because they represent a gold standard for identifying all relevant RCTs in a field<sup>8,9</sup> through highly sensitive search strategies.

We included a Cochrane SR if mechanical LBP was the target disease and rehabilitation was the intervention. Rehabilitation included all forms of therapeutic interventions defined by the National Library of Medicine as the “restoration of human functions to the maximum degree possible in a person or persons suffering from disease or injury”<sup>10</sup> delivered by health professionals of rehabilitation. SRs focusing on interventions other than therapeutic rehabilitation (e.g., prevention) or based on population subgroups (e.g., pregnancy) were excluded.

We extracted data from all studies that were included in the eligible SRs, which met the following two criteria: design was a RCT and the languages of publication were English, Italian, Spanish, or French.

### **Study selection**

Three investigators (SG, PF, GC) independently screened the Cochrane SRs (title and abstract) and, subsequently, screened the records of all potentially eligible RCTs in the SRs after the duplicates

were removed. Disagreements between investigators were resolved by consensus; if no agreement could be reached, a fourth author (LM) was consulted.

### **Data Extraction and Analysis**

We extracted the following general characteristics from each included RCT: name of journal, year of publication, country of affiliation of the corresponding author, total number of authors, and reporting of funding. To rate the completeness of intervention reporting, we adopted the checklist proposed by Schroter et al.<sup>6</sup>. This checklist outlines the items that should always be reported in an RCT investigating a rehabilitation intervention and largely overlaps with the recently developed TIDieR checklist, a template for intervention description and replication across all medical fields<sup>11</sup>. The checklist by Schroter et al. includes the following seven items: 1) setting: where the treatment was delivered (e.g., outpatients physiotherapy service); 2) provider: who delivered the treatment (e.g., two physiotherapists); 3) recipient: who received the treatment (e.g., subjects between 20 and 55 years of age with low back pain, with or without associated leg pain); 4) procedure: details about how to perform the treatment, including the sequencing of the technique (e.g., the warm-up protocol included two levels. The first level consisted of stretching, the second one the exercises for trunk muscles); 5) materials: a description of the physical or informational materials used (e.g., the protocol was adopted from Moffroid et al.); 6) intensity: the dose/duration of individual treatment sessions (e.g., each exercise was repeated 10 times. After, rest for 30 seconds to 1 minute. A session of exercise ranged from 30 to 45 minutes); and 7) schedule: the interval, frequency, duration, or timing of the treatment (e.g., sessions of three times per week for a total of 6 weeks).

We assessed the number of intervention items that were reported in an RCT ('intervention completeness'). We considered the reporting to be incomplete if one or more elements were not reported.

We used DistillerSR, a web-based database, for data extraction and management <sup>12</sup>.

Five pairs of reviewers, all actively practicing physiotherapists trained in the methodology of clinical trials, pilot tested the screening and data extraction process. The included trials were divided into five groups. Each group was assigned to a couple of reviewers. Each reviewer independently extracted the general characteristics of the studies as well as the description of the interventions used. All information was checked in double. Uncertainties were discussed and conflicts were resolved by coming to a consensus.

### **Statistical analysis**

We used percentages to describe the ‘intervention completeness’ (i.e., proportion of items in the checklist that were reported). We used the median and I-III quartiles to describe the number of adequately reported item per RCT. To investigate the impact of calendar year on each of the seven items, we performed a multivariable log-binomial regression, i.e. we fitted a generalized linear model with binomial distribution and log link, adjusting for funding (yes vs. no) and continent (as a 4 level categorical variable with America as the reference category). We explored the proper functional form for calendar year, particularly the quadratic term. For items with a significant quadratic term for year (i.e. increasing followed by decreasing trend), data for regression were curtailed at the curvature point. We estimated the effect of publication year up to this observation time, simply describing the following decreasing pattern. Results are presented as ten-year relative risks increments (RR), i.e. percentage increase in reporting the item relative to the average probability in previous decade, accounting for continent and funding, RR are reported with 95% confidence intervals (CIs). All tests were two-sided with a significance level of 0.05. Web-based screening and data extraction were supported by Distiller SR software<sup>12</sup>. All statistical analyses were performed using the R software<sup>13</sup>.



## Results

### Studies selection

We identified 11 Cochrane SRs from the Cochrane Library<sup>14-24</sup>, comprising a total of 220 RCTs. Of these, we excluded 24 articles because they were duplicates of the same article or multiple publications of the same RCTs, 7 because they did not fulfill our language inclusion criteria, and 4 because we were unable to retrieve the full text of the studies. We included the remaining 185 RCTs in the review (Figure 1).

### General characteristics

Table 1 reports the descriptive characteristics of included RCTs. The 185 identified RCTs were published across 74 journals. The top journals for the number of published articles were: *Spine* (23.2%, n=43), *Journal of Manipulative and Physiological Therapeutics* (4.8%, n=9), *Pain* and *Archives of Physical Medicine and Rehabilitation* (each 4.3%, n=8), the *British Medical Journal* (3.7%, n=7), and *Physical Therapy* (3.2%, n=6). Over half of the RCTs reported information about funding sources (56.2 %, n=104). The median number of authors included in the studies was 4 (I-III quartiles, 3-6). The median year of publication was 1998 (I-III quartiles, 1990-2004); only 8 studies were published from 1968 to 1979 (4.3%). The majority of corresponding authors came from Europe (55.6%, n=103), followed by the North and South America (27.6%, n=51).

### Completeness of intervention description

#### *How many items were satisfactorily reported?*

Figure 2 shows the distribution of the total number of items that were satisfactorily reported in each RCT. Across all RCTs, the median number of satisfactorily reported items was 5 (I-III quartiles, 3-6). The full replication of the intervention evaluated as possible in 33 RCTs (17.8%) that fulfilled

all seven items in the checklist. Three RCTs did not satisfy the reporting of any item (1.6%). Only five RCTs reported online additional materials.

### ***Which items were most satisfied?***

Figure 3 reports the percentage of RCTs satisfactorily reporting each of the seven items in the checklist. The most frequently completed items were: *recipient* (91.3%), *provider*, (81.1%), and *intervention schedule* (69.7%). The least frequently completed items were: *procedure*, (43%), *the physical or informational materials used* (48.1%), and the *setting* where the intervention was delivered (53%).

### ***Did RCTs and items improved over time?***

The percentage of trials that completely satisfied the reporting of the intervention (i.e., all seven items in the checklist) improved over time, from 14% (7 studies) in the decade 1971-1980 to 20% (75 studies) in the last decade 2001-2010. With the exception of *procedure*, all items showed an improvement trend, with more diligent reporting over time (Table 2).

For *recipient*, the improvement in reporting was statistically significant with an estimated 5% increase in the percentage of studies reporting the item for every ten years (10-year RR 1.05; 95% CIs 1.01-1.09). *Intensity* and *schedule* were curvilinear: the trend increased until the early 2000s and decreased thereafter. This change in trend was statistically significant. Limiting the analysis to the studies published before 2000, both *intensity* and *schedule* had a significant improvement over time (10-year RR 1.37; 95% CI 1.07-1.77 and 1.26; 95%CI 1.02-1.57, respectively), reaching 80% and 90% of adequate reporting, respectively. They decreased after 2000, reaching 63 and 61% in the 2005-2009 period.

### *Is a satisfactory reporting associated with country and funding?*

Supplemental Digital Content in table 1 shows detailed results for continent and funding.

Approximately 25% of the studies from Asia and Oceania and one-sixth of the studies from America and Europe met all reporting criteria. At log-binomial regression, country was statistically significant (likelihood ratio test) only for *provider* and *intensity* ( $p=0.046$  and  $0.039$ ). For *provider*, the RR for Oceania compared to America was 1.22 ( $p=0.016$ ), while, for *intensity*, Europe had a RR of 0.73 ( $p=0.006$ ) compared to America. More than half of the 185 RCTs (56.2%) reported sufficient information about funding. We did not find any significant association between a checklist item and the reported funding in the regression models.

### **Discussion**

In our study, we found that only a minority, about one fifth, of all RCTs on LBP rehabilitation adequately described all elements of the intervention. On average, each RCT completely reported five items. The less frequently described aspects were *procedure*, *materials*, and *setting*, while *provider*, *recipient* and *schedule* were at the top. Our data highlight significant and interrelated trends for better reporting. Most items improved over time, with the exception of *procedure*, the only item showing a negative, even if not statistically significant, trend over time. An unexpected finding was the relative decline in the reporting of *materials*, *schedule* and *intensity* over the last years investigated. All of the seven items are relevant for the successful transfer of research results to rehabilitation practice; researchers should endeavour to provide clear and complete reporting of these elements to increase the impact and relevance of their studies. Particularly, the omission of information on intervention *procedure*, if previously unpublished or simply adapted by the research team, could cause practitioners to adopt incorrect practices that may be ineffective, or even cause harm. These results show a mediocre reporting capability, even though a positive evolution seems to have started.

The unsatisfactory description of interventions across rehabilitation RCTs in our review is highly consistent with previous studies across different medical fields. Pino et al. analysed a sample of 150 RCT protocols focused on patient education interventions and found that less than one fifth were adequately described<sup>25</sup>. In a sample of RCTs published on the authoritative British Medical Journal, the less frequently described aspects of the rehabilitation interventions were the *procedure* and the *physical or informational materials used*<sup>6</sup>. Glasziou et al. compared the reporting of non-pharmacological and pharmacological interventions: both groups showed room for improvement, although the completeness of intervention descriptions was poorer in the non-pharmacological interventions (29% versus 67% of adequate reporting)<sup>5</sup>.

There are several factors that might explain this poor reporting. On one hand, the nature of rehabilitation interventions itself. First, rehabilitative interventions might lack a strong rationale and solid theoretical construct<sup>26</sup>. Non-pharmacologic interventions do not mature from early phases of research (i.e. phase I) to late phases (phases III and IV). Researchers, moreover, have limited evidence gains about the optimum structure, timing, and content of rehabilitation interventions across phases<sup>27</sup>. Second, trials in rehabilitation usually test complex interventions involving several components<sup>28</sup> that might be difficult to standardize and administer consistently to all patients<sup>29</sup>.

Finally, there might be a gap between who administers the intervention and who writes the paper: the health professionals performing the intervention are not involved in the reporting. Trials can be well conducted, but badly reported.

On the other hand, shortcomings in reporting can also relate to journals and their editorial policies. Only in recent years have guidelines for transparent reporting been introduced. The Enhancing the QUALity and Transparency Of health Research (EQUATOR) initiative and the Consolidated Standards of Reporting Trials (CONSORT) Statement are gaining momentum across clinical fields<sup>30</sup>. However, improvements in quality might take longer. Even if most journals' *Instructions to Authors* recommend the use of specific standards for the reporting of interventions, only a minority

of the journals require their completion<sup>31,32</sup>. Additionally, word restrictions may force authors and

editors to leave out details on the intervention<sup>33</sup>. There has been a sudden growth in the number of journals publishing LBP trials. Across 33 years (1968-2001) only 41 different journals published more than one RCT. Conversely, between 2002 and 2009 we detected a total of 74 journals publishing more than one RCT on low back pain interventions. This sudden increase may also be associated with the lower quality of reporting of the published research. Particularly, new journals may have inexperienced editors and this phenomenon might also explain why the completeness of some reporting items, such as *materials*, has declined in the last decade.

Journals can help to improve the problem of incomplete intervention reporting by providing access to online supplementary materials and specific instructions to authors. Ideally, the first publication of a primary study should include a comprehensive description of the intervention used. This, however, may not be feasible in studies, for example, with manual procedures or extensive training materials. Because *materials* and *procedure* could add significantly to the length of papers, we suggest that editors encourage the use of links on the institutional website of the authors or funders; journals should request this information at the time of publication since researchers might retire, move, or not respond after publication. Journals should, moreover, require authors to comply with reporting guidelines from the protocol stage (SPIRIT initiative<sup>37</sup>), using checklists such as the Schroter et al.<sup>6</sup>, the CONSORT<sup>7</sup>, and the TIDieR<sup>11</sup>. Editors and peer reviewers need to verify authors' compliance with the instructions, actively checking for missing details before publication. All these action, together, will help the physical therapy community to better define, replicate, and disseminate interventions, ensuring consistent efficacy across patients.

### **Limitations**

Our study has several limitations. First, we explored only rehabilitative interventions for LBP, in general, excluding conditions such as pregnancy as well as treatments that were non-therapeutic (e.g., orthosis). Second, our sample of studies spans across several decades. The appropriateness of

examining old RCTs may be questioned. Finally, we included only RCTs written in English, Italian, Spanish, and French languages. Anyway, the number of excluded articles was low (n=7 RCTs).

## **Conclusion**

Despite a positive trend over time in the completeness of intervention reporting in rehabilitation, only a minority of trials provided a complete intervention reporting across all items. Transparent and accurate reporting of interventions is a crucial step to facilitate the transfer of research findings to community rehabilitation practitioners and to reduce the waste of research budget.

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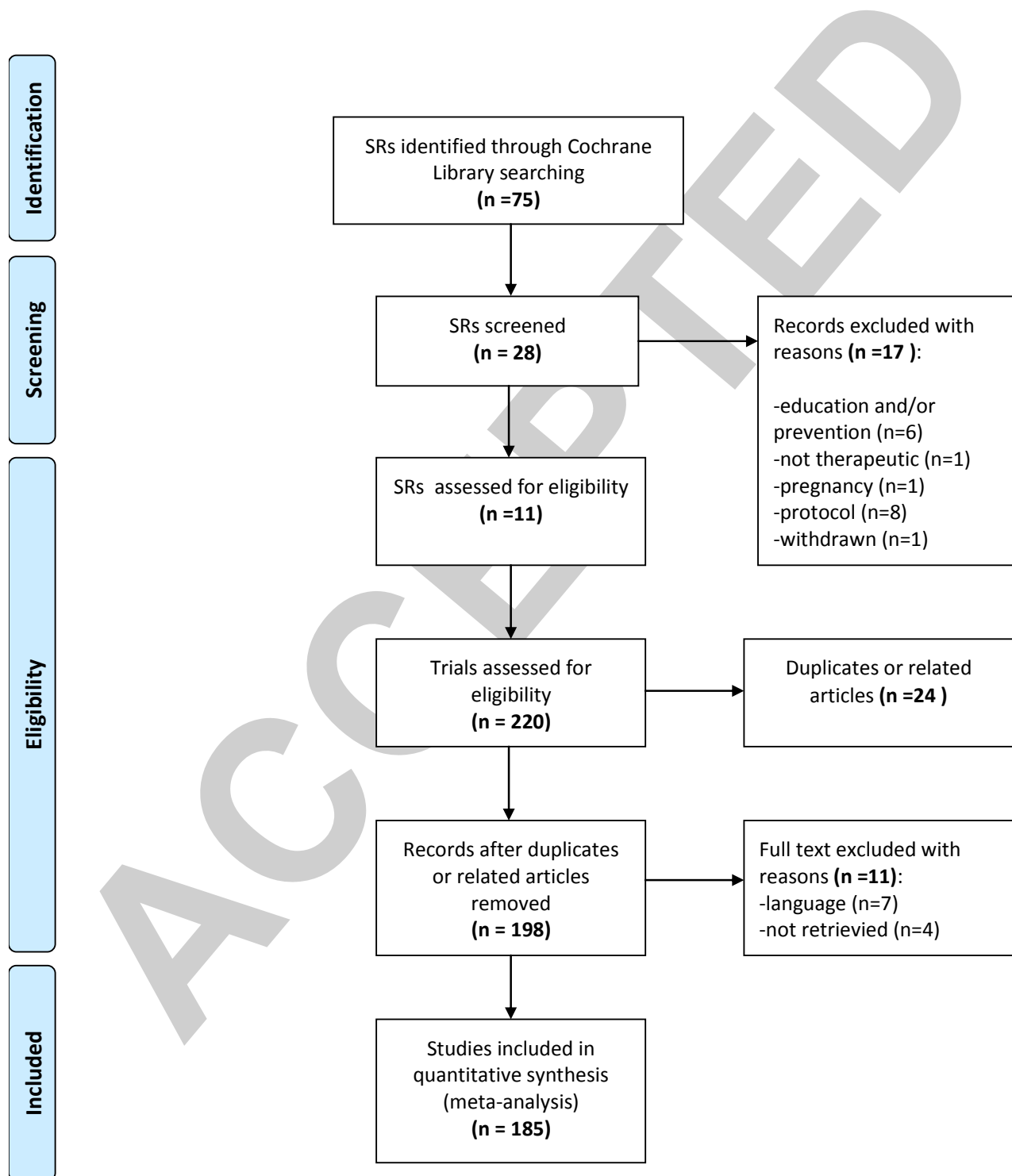


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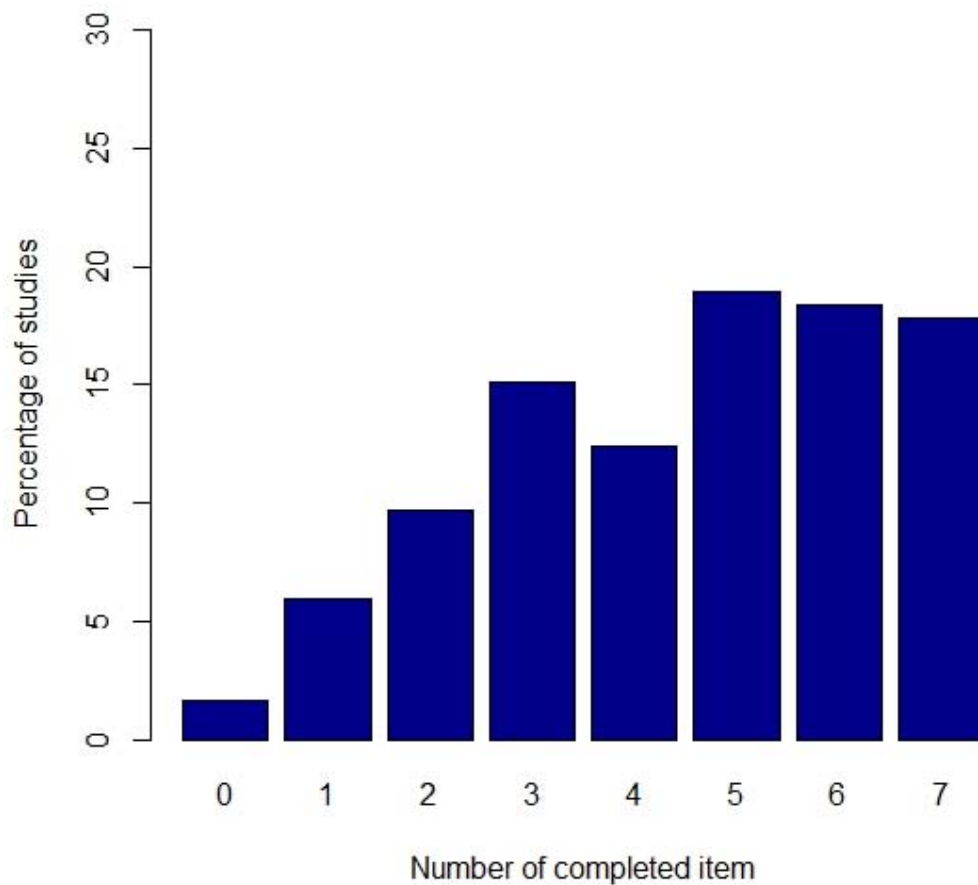
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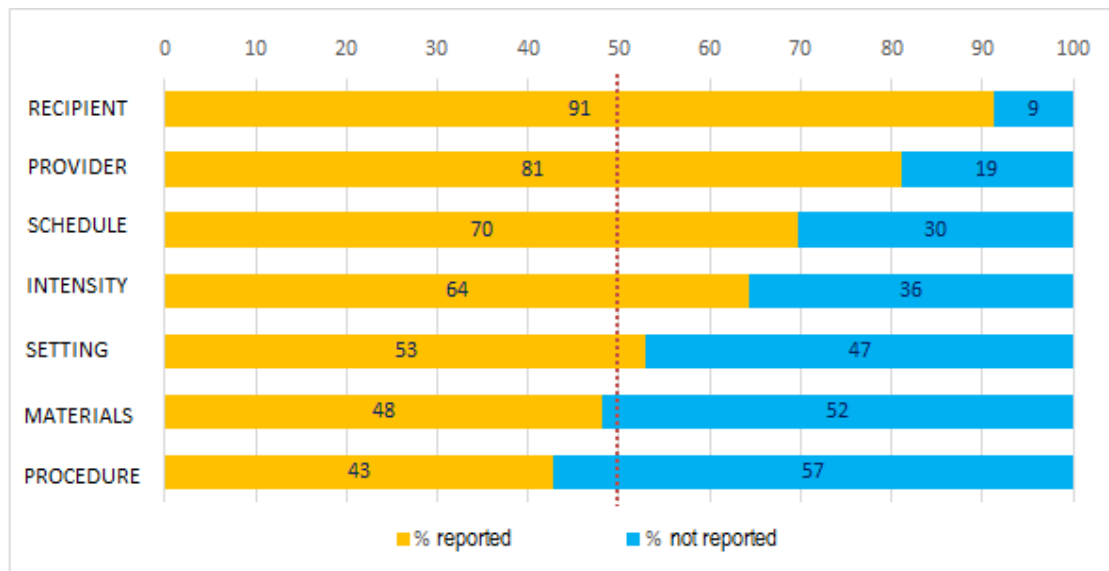
**Figure 1.** Flow diagram describing the selection process of the 185 RCTs on interventions for low back pain included in the study.



**Figure 2.** Overall completeness of interventions reporting. Relative frequency distribution of the number of items (out of seven total in the checklist) that were satisfactorily reported in each RCT.



**Figure 3.** Percentage of studies providing reported information or not reported information in each intervention description item.



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**Table 1.** Descriptive characteristics of the included 185 RCTs.

	Number	Relative frequency %	Median N° of adequately reported item (I-III quartiles)
<b>RCTs involved per Continent</b>			
Europe	104	56.2	5.0 (3.0-6.0)
North and South America	51	27.6	5.0 (3.0-6.0)
Asia	19	10.3	5.0 (3.0-6.0)
Oceania	11	5.9	6.0 (4.0-6.5)
Africa	0	0	0
<b>RCTs published into the first 5 most frequent journals (total number of involved journal n=74)</b>			
Spine	43	23.2	6.0 (5.0-7.0)
Journal of Manipulative and Physiological Therapeutics	9	4.8	4.0 (3.0-5.0)
Pain	8	4.3	5.0 (3.8-4.5)
Archives of Physical Medicine and Rehabilitation	8	4.3	5.5 (4.3-7.0)
British Medical Journal	7	3.7	3.0 (1.0-3.0)
Physical Therapy	6	3.2	3.5 (3.0-5.5)
Other Journals	104	56.2	5.0(3.0-6.0)
<b>Funding</b>			
RCTs not reporting	81	43.8	5.0(3.0-6.0)
RCTs reporting	104	56.2	5.0(3.0-6.0)

Table 2.

	(a) Percentages of RCTs describing each item by publication year							(b) Models' results		
	1968-79	1980-84	1985-89	1990-94	1995-99	2000-04	2005-09	RR for 10 year increase	P value	
<b>Setting</b>	38	46	47	42	54	66	55	1.14	0.120	
<b>Recipient</b>	88	85	84	84	94	98	95	1.05	0.008	
<b>Provider</b>	75	69	74	81	86	83	84	1.03	0.430	
<b>Procedure</b>	62	38	26	52	57	44	26	0.89	0.219	
<b>Materials</b>	38	23	37	55	57	51	47	1.11	0.270	
<b>Intensity*</b>	25	38	47	77	63	80	63	1.37	0.014	
<b>Schedule*</b>	38	46	53	87	66	90	61	1.26	0.033	

RRs can be seen from the reported percentages, for Intensity and Schedule there was a curvilinear trend with an increase until 2000 and a decrease thereafter, and this change in trend (coefficient of the quadratic term for year) was statistically significant in the regression. In the table, we report the RR for year obtained stopping the analysis at 2000.

**Supplemental Digital Content, Table 1.** Number of RCTs per continent with a complete reporting.

	North & Sud America	Europe	Asia	Oceania
	51(27.6%)	103(55.7%)	19(10.3%)	12(6.5%)
Provider	39(76.5%)	87(84.5%)	12(63.2%)	12(100%)
Recipient	42 (82.4%)	97(94.2%)	18 (94.7%)	12(100%)
Schedule	36(70.6%)	69(67%)	15(78.9%)	9(75%)
Intensity	38(74.5%)	57(55.3%)	15(78.9%)	9(75%)
Materials	25(49%)	47(45.6%)	11(57.9%)	6(50%)
Procedure	19(37.3%)	43(41.7%)	12(63.2%)	5(41.7%)
Setting	39(76.5%)	87 (84.5%)	12(63.2%)	12(100%)
All 7 items completed	9(17.6%)	16(15.5%)	5(26.3%)	3(25%)