

ORIGINAL ARTICLE

A methodological review revealed that reporting of trials in manual therapy has not improved over time

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Abstract

Objective: The aim of this review was to evaluate a selection of major reporting aspects in manual therapy (MT) trials, before and after the publication of the CONSORT extension for nonpharmacological trials (CONSORTnpt)

Study Design and Setting: We randomly selected 100 MT trials published between 2000 and 2015 and divided them into a pre-CONSORTnpt ($n = 50$) and a post-CONSORTnpt ($n = 50$) group. We extracted data on relevant issues of internal validity, reliability, and description of interventions. Two authors extracted data independently. Percentages were used for descriptive analyses, and Fisher's exact test and the chi-square test were used for group comparisons.

Results: Six different types of MT interventions with up to 20 controls were analyzed. The most common populations/conditions studied were healthy subjects and subjects with lower back or neck pain. Over 70% of studies included multi-session interventions, and 42% of studies reported long-term followup. The only significant differences between groups were the inclusion of a flowchart diagram, the estimated effect size, precision descriptions, and the description of intervention procedures.

Conclusion: Our findings suggest that trials in MT show poor reporting even after the availability of standardized guidelines. © 2020 Elsevier Inc. All rights reserved.

Keywords: CONSORT; Manual therapy; Reporting; Quality; Guidelines; Nonpharmacological

1. Background

Manual therapy (MT) is a physical treatment used by a variety of therapists to treat, mainly musculoskeletal pain and disability. It includes massage and soft tissue techniques, joint mobilization, and manipulation [1]. Since its origin, methods and approaches have evolved greatly [2].

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Currently, there is evidence of the effectiveness of MT in the musculoskeletal pain field for pathologies, such as lower back pain, carpal tunnel syndrome, and knee and hip osteoarthritis, with the most robust evidence obtained when patients are classified by subgroups [3,4].

However, in spite of a growing interest in MT, there is an important lack of quality studies and high-quality evidence of its effectiveness [5], as reflected in the conclusions of numerous systematic reviews [1,6–14]. A possible explanation lies in the methodological difficulties involved in performing high-quality randomized controlled trials (RCTs) for certain medical disciplines that involve what is referred to as complex and nonpharmacological interventions [15,16]. Physical therapies in general and MT, in particular, are considered complex interventions due to the fact that they include different therapeutic modalities in the same intervention [17], assuming that the

What is new?**Key findings**

- Manual therapy trials show poor reporting quality.

What this adds to what was known?

- The implementation of reporting guidelines could have a minimal impact on this field.

What is the implication and what should change now?

- Guidelines specifically adapted to each kind of nonpharmacological intervention could potentially enhance reporting quality and research methods.

combination of different modalities is more effective than the sum of the parts [18–20]. Detailed reporting of such complex interventions is, therefore, crucial for the evaluation of the applicability of findings to routine practice [21].

Between 1996 and 2010, the Consolidated Standards for Reporting Trials (CONSORT) Statement and revised versions were published to significantly improve the quality of RCT reporting [22]. The CONSORT Statement has been endorsed by prominent general and specialty medical journals and leading editorial organizations. The above-said endorsement has been associated with an improvement in the quality of reporting [22–24].

In 2014, 28 rehabilitation-based journals elected to take a more aggressive stance toward the implementation of reporting guidelines in order to enhance the quality of scientific reports in this field [25]. However, recent research shows that, in spite of gradual improvement over time, there is still a need to improve both methodological quality and statistical reporting [26]. Focusing specifically on the MT literature, the evidence suggests that the quality of reporting has not improved in recent years [27], which, in turn, would suggest that the current use of CONSORT guidelines is not optimal. However, the same evidence states that these guidelines include several items with unclear definitions, leading to unreliable reporting in the MT literature [27].

In 2008, the CONSORT extension for nonpharmacological trials (CONSORTnpt), a guideline developed for psychotherapy, surgical, and rehabilitation trials, was published to respond to specific challenges that were not adequately addressed in RCT reporting [28]. However, the impact of this extension has not been assessed. The aim of this review was to evaluate a selection of major reporting aspects in manual therapy (MT) trials, before and after the publication of CONSORTnpt.

2. Methods

2.1. Eligibility criteria

RCTs published in the field of MT were included. Criteria for inclusion were that at least one of the

interventions (experimental or control) should include some form of MT. Articles not written in English, with designs other than RCTs and studies that referred to posters and oral communications, were excluded (Fig. 1).

2.2. Search strategy

We searched trials from 2000 to 2015 and classified them into two groups by year of publication. The pre-CONSORTnpt group (pre-C) was composed of articles published between 2000 and 2008, and the post-CONSORTnpt group (post-C) was composed of articles published between 2009 and 2015.

We searched the Cochrane Collaboration Trials Register (CENTRAL), as the most comprehensive source of trials [29,30], and the most valid one to retrieve trials on physical therapy [31]. The search strategy, based on the narrow search strategy proposed by Pillastrini et al. (2014) [32], is described in Appendix 1.

2.3. Sample size calculation

The sample size was calculated to determine the number of articles we needed to analyze in order to detect a 4-point pre-C/post-C difference (representing a relative change of approximately 15% in the mean number of yes responses). A nonparametric analysis was performed using the Mann-Whitney U test. We assumed an $\alpha = 5\%$ for a bilateral approximation and a minimum statistical power of 80% (GRANMO v.7.12). The calculations resulted in 42 articles for each study group, increased to 50 to improve accuracy ($n = 100$).

2.4. Data extraction

We assessed the reporting of MT RCTs focusing on the most relevant issues related to internal validity, reliability, and description of interventions [33–35]. Therefore, we designed a data extraction form to collect these issues, which contained selected items from CONSORTnpt [28], “Methods” and “Results” sections, and from the Template for Intervention Description and Replication (TIDieR) [36]. We completed the form with additional items defined by the researchers related to the trials’ characteristics and additional issues related to blinding.

We piloted the form with five RCTs reaching a substantial agreement between data extractors (range 77.30% and 83.20%; Kappa value 0.61–0.71; $P < 0.001$) [37]. After piloting, the data extraction form was optimized to include 44 items, response criteria were agreed by the review group, and instructions were provided for supporting the reviewers’ task (Appendix 2). Each article was reviewed by pairs made up of the principal investigator of the study (GA) and one other member of the review group (AF, MS, CF, GU, IS). Disagreements were discussed and resolved by the pairs.

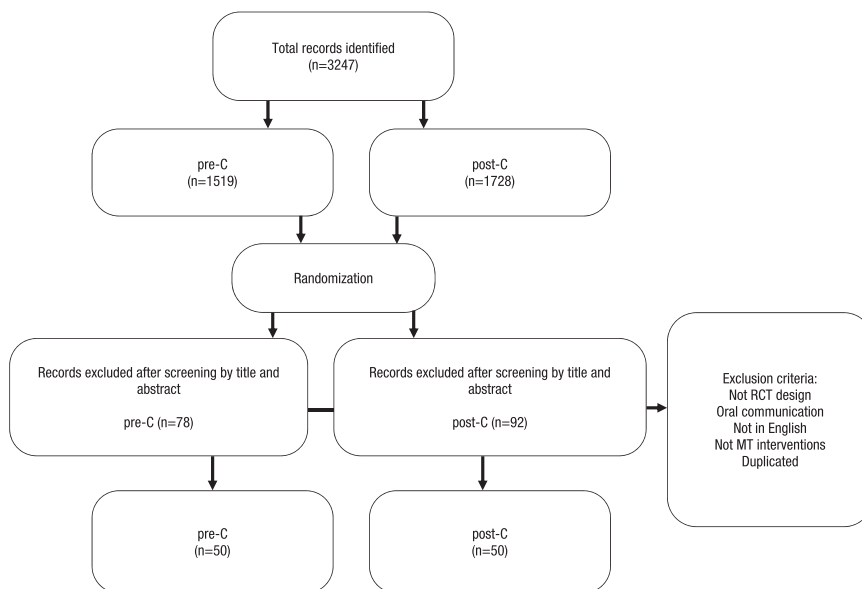


Fig. 1. Study selection flowchart.

2.5. Data analysis

The analysis was performed using IBM-SPSS Statistics for Windows, Version 25.0. (Armonk, NY, USA: IBM Corp). Categorical variables were descriptively presented as percentages. The pre-C and post-C groups were compared using the Fisher exact test (comparison of dichotomous variables) and the chi-square test (simultaneous comparison of categorical variables).

3. Results

3.1. Search results

The search yielded 1,519 pre-C and 1,728 post-C article references that were randomly ordered using the Microsoft Excel random number generator. The first 50 references in each group were selected based on a reading of the title and abstract, and by applying the eligibility criteria (Fig. 1).

3.2. Article description

Of the 100 articles analyzed, 77 corresponded to single-center studies (35 pre-C and 42 post-C) and 23 to multi-center studies (14 pre-C and 9 post-C). The mean number of study participants was 158 (median = 71, SD = 273, range 6-1340) in the pre-C group and 78 (median = 60, SD = 60, range 16-241) in the post-C group. The sample of analyzed articles included both manual techniques and treatments.

Table 1 summarizes the types of manual and control interventions. Some studies evaluated therapeutic packages in which MT was provided alongside with other interventions. In these cases, the specific MT modality was used to classify the multimodal intervention studies.

Table 1. Types of experimental and control interventions (n = 100)

Experimental interventions	N	Pre-C	Post-C
Soft tissue techniques	31	12	19
Joint mobilization	22	11	11
Spinal manipulation techniques	21	11	10
Chiropractic treatments	13	10	3
Osteopathic manipulative treatment	6	2	4
Acupressure-reflexology	7	4	3
Total	100	50	50
Control interventions			
Usual care	23	12	11
Exercise	21	13	8
Sham intervention	18	8	10
Joint mobilization	13	2	11
No intervention	10	6	4
Medication	6	4	2
Electrotherapy	5	2	3
Spinal manipulation techniques	3	3	0
Soft tissue techniques	4	2	2
Light massage/touch	3	0	3
Sham electrotherapy	3	0	3
Chiropractic treatment	3	3	0
Advice/education	2	1	1
Placebo capsules	1	1	0
Behavioral graded activity program	1	0	1
Acupuncture	1	1	0
Functional task practice	1	1	0
Device	1	1	0
Vibration therapy	1	1	0
Classification-based cognitive functional therapy	1	0	1
Total	121	61	60

The experimental interventions were classified in six categories: (a) soft tissue techniques, which included studies that evaluated any of the following: massage, stretching, muscle energy techniques, ischemic compression, myofascial/positional release techniques, counter-strain techniques, neuromyotherapy, and manual lymphatic drainage; (b) joint mobilization, which included studies that evaluated any joint mobilization technique performed on the back or in peripheral joints (without thrust); (c) spinal manipulation therapy (SMT) techniques, which included studies that evaluated spinal high-velocity low-amplitude (HVLA) techniques without explicit mention of any specific therapeutic modality, (d) chiropractic treatments, (e) osteopathic manipulative treatment (OMT), and (f) acupressure or reflexology. The studies in (d) and (e) were allocated to these individual categories irrespective of whether or not HVLA techniques were used.

In some studies, more than one control intervention was used (Table 1). In the pre-C group, ten articles used more than one control (nine articles with two controls and one article with three controls), and in the post-C group, eight articles used more than one control (six articles with two controls and two articles with three controls).

Table 2 summarizes the details of the studied participants/conditions. The most frequent studies were those carried out with healthy/asymptomatic subjects, in most cases, volunteer subjects recruited in the educational or university

institutions, where the studies were performed. The most frequent health problems were lower back pain and neck pain.

Treatment consisted of more than one session in 71% of the studies. For the pre-C group, 13 articles analyzed single-session interventions, and 37 articles analyzed multi-session interventions. For the post-C group, there were 16 and 34, respectively. Regarding participant follow-up, the long-term followup was defined as at least one measurement 3 months after the end of the intervention. According to this criterion, 42% of the articles reported long-term followup, with no significant differences between the groups ($P = 0.31$). Another 42% of the sample only reported immediate effects, 60% in the post-C group, compared to 40% in the pre-C group.

Fig. 2 depicts the results of an overall comparison regarding adequately reported items. The mean (SD) in the pre-C group vs. the post-C group was 18.87 (4.93) vs. 19.98 (4.94), with no statistically significant overall difference between the two groups ($P = 0.26$ [−3.06 to 0.85]). Regarding internal validity and reliability, only two items showed significant differences between the two groups: “inclusion of a diagram showing participant flow through study stages” ($P = 0.016$ [−44.6 to −7.4]) and “details of the estimated effect size and precision for primary and secondary outcomes by group” ($P = 0.021$ [−33 to −6.9]). Regarding the reporting quality of interventions, there was a significant difference between the two study groups for just the item “Procedures” ($P = 0.01$ [−32.1 to −7.8]).

Table 3 shows comparative results of items evaluating internal validity and reliability. Table 4 shows comparative results of intervention descriptions.

Additionally, we performed a post-hoc sensitivity analysis, excluding studies published 2 years after the CONSORTnpt. The analysis had no major impact in relation to the overall comparison but showed changes in two specific items. From the three items that initially showed statistical differences, one was no longer a significant *description of effect size and precision for primary and secondary outcomes*, and another one reached significance *provider expertise description*. We include a detailed analysis in Appendix 3.

4. Discussion

We conducted a study to assess the changes over time in the quality of reporting in MT trials. For this purpose, we obtained data on how trials described relevant issues of validity, reliability, and the intervention description according to items mainly captured from reporting guidelines and compared two time periods to assess the impact of one of them, that is, CONSORTnpt. Overall, our results indicate that the methodological quality of MT trial reporting is poor and has not improved over time, except for a few

Table 2. Types of participants/conditions ($n = 100$)

Participants/conditions	N	Pre-C	Post-C
Healthy/asymptomatic	12	4	8
Lower back pain	8	5	3
Acute	5	5	0
Chronic	9	4	5
Neck pain	6	4	2
Acute (including acute whiplash)	5	2	3
Chronic	4	2	2
Pregnancy/gynecological problems	7	3	4
Children- and infant-related disorders	6	2	4
Shoulder-related disorders	4	2	2
Osteoarthritis	4	1	3
Cardiac and vascular problems	3	1	2
Stroke-related disorders	3	2	1
Headache	3	1	2
Postoperative conditions	3	2	1
Spinal pain	2	1	1
Sports-related conditions	2	2	0
Craniofacial disorders	2	1	1
Plantar heel pain	2	1	1
Lateral epicondylitis	2	0	2
Other	8	5	3
Total	100	50	50

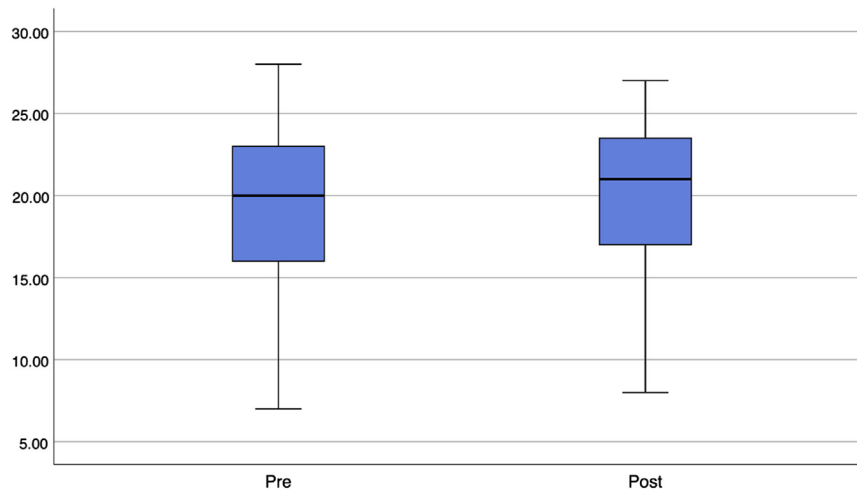


Fig. 2. Overall comparison for items adequately reported by the pre-C and post-C groups.

items. These findings could suggest that reporting guidelines have not had a significant impact on reporting quality years after its publication. Some issues have been highlighted as relevant to improve both the quality and reporting of MT research [33–35].

Our results show that despite some improvements in participant, practitioner, and setting descriptions in trials of the post-C group, there is still a need to provide more detailed descriptions. In MT studies, the description of the interventions is especially important, and guidelines, such as TIDieR [36], have been designed to improve this reporting [21]. In fact, CONSORTnpt has included most of its items in its update [38]. Intervention descriptions need to be completed very carefully in order to allow intervention evaluation and replication, as otherwise, the relevance of improving patient care is reduced, and resources are wasted [39,40]. Our results show an improvement in the description of procedures (Table 4).

In almost 60% of the analyzed MT trials, information on sample size calculation was not available, with no differences between the pre-C and post-C groups. MT trials are often based on small samples, which, in turn, usually results in type II error caused by low statistical power [33]; note that only 33% of our sample had $n \geq 100$ (38% pre-C and 28% post-C). The mean number of participants was 118, and the comparison between pre-C and post-C groups points to a falling trend in the median sample size. If we look at the literature on interventions for chronic lower back pain, the number of RCTs has risen exponentially over the past 30 years, and still there does not appear to be a corresponding increase in sample size [41]. For SMT used to treat lower back and neck pain, Rubinstein et al. [42] found that although the sample size appeared to increase over time, it did not do so to a statistically significant degree (overall $P = 0.79$). The same authors also found a linear trend over time in the odds of sample size being calculated a priori, a fact that may point to an improvement in this particular aspect.

Since nonpharmacological interventions, such as MT, are typically used to treat chronic conditions [43–45], treatment may last several weeks, so outcome evaluation of necessity includes long-term followup. Trialists, therefore, need to be aware of the fact that a small or underpowered sample in an RCT with long-term followup can potentially be affected by attrition bias. Information on attrition and its impact on baseline imbalances have been proposed as an item for inclusion in CONSORT guidelines [46], but no specific mention has been included in the updated version of the CONSORTnpt [38].

Regarding randomization and allocation concealment, full information was provided in 64% of the articles, with no differences between groups. We argue that this is an easy improvement to apply, as it poses none of the methodological challenges posed by other trial design requirements.

Blinding is critical to all nonpharmacological interventions [47] and is considered to be a major challenge in rehabilitation and physical medicine trials [33–35,48,49]. A modification included in the updated 2017 version of the CONSORTnpt (point 11c) recognizes this major difficulty and recommends to at least describe attempts to limit bias when blinding is not possible [38]. Table 5 confirms that blinding in MT trials is an aspect that has hardly improved over the years, with a favorable trend only evident for outcome evaluator blinding. Improvements in blinding strategies are probably linked to the use of better controls (sham or placebo interventions), another aspect, which MT trials need to improve [50,51]. Moreover, knowing the crucial role of contextual factors in nonpharmacological intervention effects [52–54] and bearing in mind that blinding success is rarely tested [55], attempts to assess whether masking was effective should be proposed as a good methodological practice for MT trials [56].

In our sample, 59% of the articles included a flowchart diagram and a statistically significant difference was found

Table 3. Comparative results related to internal validity and reliability reporting items

Description	% Total YES	NA	Pre-C YES	Post-C YES	% Change	P	95% CI
Eligibility criteria for participants are stated	97%	—	47 (94%)	50 (100%)	6%	0.61	[−12 to 0.5]
Eligibility criteria for settings and locations are stated (single-center)	51%	—	22 (44%)	29 (58%)	14%	0.31	[−33.4 to 5.4]
Eligibility criteria for settings and locations are stated (multicenter)	15%	77%	9 (18%)	6 (12%)	−6%	0.32	[−7.9 to 19.9]
Eligibility criteria for persons performing the intervention are stated	56%	—	23 (46%)	33 (66%)	20%	0.07	[−39.1 to 0.9]
Objectives and hypotheses are stated	100%	—	50 (50%)	50 (50%)	0%	—	—
Primary outcome measures are clearly defined	47%	—	24 (48%)	23 (46%)	−2%	0.84	[−17.6 to 21.6]
Methods are included that enhanced measurement quality	82%	4%	40 (80%)	42 (84%)	4%	0.51	[−19 to 11]
How sample size was determined is indicated and, when applicable, details are provided of whether and how clustering by care provider or center was done	41%	—	17 (34%)	24 (48%)	14%	0.22	[−33.1 to 5]
A random allocation sequence method was used	64%	—	29 (58%)	35 (70%)	12%	0.40	[−30.7 to 6.6]
Care provider allocation to each trial group is described	4%	47%	2 (4%)	2 (4%)	0%	—	[−7.6 to 7.6]
The method used to implement the random allocation sequence is described	51%	—	22 (44%)	29 (58%)	14%	0.31	[−33.4 to 5.4]
The persons who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions are indicated	36%	—	16 (32%)	20 (40%)	8%	0.53	[−26.8 to 10.8]
Participant blinding to group allocation is indicated	32%	—	14 (28%)	18 (36%)	8%	0.52	[−26.2 to 10.2]
Whether the persons performing the intervention were blinded to group allocation is indicated	3%	—	2 (4%)	1 (2%)	−2%	0.61	[−4.6 to 8.6]
Whether the persons evaluating outcomes were blinded to group allocation is indicated	60%	—	26 (52%)	34 (68%)	16%	0.22	[−34.9 to 2.9]
Whether the persons performing co-interventions were blinded to group allocation is indicated	10%	68%	5 (10%)	5 (10%)	0%	0.82	[−11.8 to 11.8]
Statistical methods to compare groups for primary outcomes are described	100%	—	50 (50%)	50 (50%)	0%	—	—
Methods for additional analyses (subgroup analyses and adjusted analyses) are described	39%	41%	21 (42%)	18 (36%)	−6%	0.73	[−13.1 to 25.1]
Details of whether and how clustering by care provider or center was done (when applicable) are provided	3%	80%	2 (4%)	1 (2%)	−2%	0.10	[−4.6 to 8.6]
Participant flow through stages is described	59%	—	23 (46%)	36 (72%)	26%	0.016 ^a	[−44.6 to −7.4]
The number of randomly allocated participants is indicated	100%	—	50 (50%)	50 (50%)	0%	—	—
The number of participants receiving the intended treatment is indicated	97%	—	48 (96%)	49 (98%)	2%	1.0	[−8.6 to 4.6]

(Continued)

Table 3. Continued

Description	% Total YES	NA	Pre-C YES	Post-C YES	% Change	P	95% CI
The number of participants completing the study protocol is indicated	85%	—	42 (84%)	43 (86%)	2%	1.0	[−16 to 12]
The number of participants analyzed for the primary outcome is indicated	95%	—	48 (96%)	47 (94%)	−2%	0.36	[−6.5 to 10.5]
Protocol deviations from study as planned are indicated	5%	30%	2 (4%)	3 (6%)	2%	0.58	[−10.5 to 6.5]
The number of care providers and centers performing the intervention in each group is indicated	34%	—	15 (30%)	19 (38%)	8%	0.53	[−26.5 to 10.5]
The number of patients treated by each care provider and center is indicated	17%	—	8 (16%)	9 (18%)	2%	0.83	[−16.7 to 12.7]
Losses and exclusions after randomization are indicated	89%	—	44 (88%)	45 (90%)	2%	1.0	[−14.3 to 10.3]
Reasons for losses and exclusions after randomization area described	51%	—	25 (50%)	26 (52%)	2%	0.99	[−21.6 to 17.6]
The dates defining recruitment are indicated	52%	—	22 (44%)	30 (60%)	16%	0.16	[−35.3 to 3.3]
The dates defining follow-up are indicated	71%	—	37 (74%)	34 (68%)	−6%	0.66	[−11.7 to 23.7]
The baseline demographic and clinical characteristics of each group are provided	91%	—	43 (86%)	48 (96%)	10%	0.31	[−21 to 10.5]
The number of participants (denominator) for each group included in each analysis is indicated	97%	—	48 (96%)	49 (98%)	2%	1.0	[−8.6 to 4.6]
Whether or not analysis was by intention-to-treat is indicated	34%	—	18 (36%)	16 (32%)	−4%	0.67	[−14.6 to 22.6]
For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision are described	86%	—	38 (76%)	48 (96%)	20%	0.021 ^a	[−33 to −6.9]
Other analyses are described, including subgroup analyses and adjusted analyses, with an indication that they are prespecified or exploratory	38%	53%	22 (44%)	16 (32%)	−12%	0.37	[−6.8 to 30.9]
All important harms and unintended effects in each group are indicated	47%	—	22 (44%)	25 (50%)	6%	0.69	[−25.5 to 13.5]

NA, not applicable.

^a $P < 0.05$.

between the two study groups. As shown in Table 6, the number of randomly allocated participants and information on missing data, dropouts, and losses to followup were generally well reported.

Another important item is “stating the number of participants included in each analysis and whether the analysis was by intention-to-treat” (ITT). Although the former was reported in 97% of the articles, only 34% of articles referred to ITT analyses, which, in fact, is information that is infrequently included in publications on physical therapies [57]. Trials can fail to meet this criterion by not using ITT analysis, by not reporting that ITT analysis was used or by misinterpreting the definition of ITT analysis. Furthermore, full follow-up and equal final group sizes do not guarantee the quality of ITT analyses [58]. Given intrinsic MT characteristics, RCTs often aim to evaluate the

effectiveness (rather than the efficacy) of interventions, typically by applying a pragmatic approach to the design. It has been suggested that the result analysis should apply the same pragmatic approach, that is, reflecting clinical practice as faithfully as possible, as the ITT analysis should provide an indication of the clinical benefits of the treatment [59]. For the above reasons, we suggest that inclusion in the published report of a formal statement regarding the type of analysis should be strongly recommended. While data can be imputed alongside an ITT analysis, the fact remains that none of any original articles on ITT analysis, the Cochrane Handbook, the CONSORT statement, or the PE-Dro Scale specifically recommend, including this information [58]. In our sample, the imputation of missing data was described in just half of the 66% of articles that described dropout rates.

Table 4. Comparative results related to intervention description reporting items

Description	% Total YES	NA	Pre-C YES	Post-C YES	% Change	P	95% CI
Provide the name or a phrase that describes the intervention	99%	—	48 (96%)	50 (100%)	4%	0.49	[−9.4 to 1.4]
Describe any rationale, theory, or goal of the elements essential to the intervention	99%	—	48 (96%)	50 (100%)	4%	0.49	[−9.4 to 1.4]
Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)	100%	—	—	—	—	—	—
Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	88%	—	39 (78%)	49 (98%)	20%	0.01 ^a	[−32.1 to −7.8]
For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given	53%	—	22 (44%)	31 (62%)	18%	0.16	[−37.2 to 1.2]
Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	100%	—	—	—	—	—	—
Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	36%	—	14 (28%)	22 (44%)	16%	0.14	[−34.6 to 2.5]
Describe the number of times the intervention was delivered and over what period of time, including the number of sessions, their schedule, and their duration, intensity, or dose	92%	—	43 (86%)	49 (98%)	12%	0.15	[−18.9 to 2.2]
If the intervention was planned to be personalized, titrated or adapted, then describe what, why, when, and how	34%	30%	17 (34%)	17 (34%)	0%	0.47	[−18.6 to 18.6]
If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)	5%	89%	1 (2%)	4 (8%)	6%	0.27	[−14.5 to 2.4]
Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	23%	66%	11 (22%)	12 (24%)	2%	0.58	[−18.5 to 14.5]
Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	20%	70%	10 (5%)	10 (5%)	0%	0.74	[−15.7 to 15.7]

NA, not applicable.

^a $P < 0.05$.

“Information on effect size and precision by group” was provided in 86% of our sample, with a significant improvement in post-C articles. Nonetheless, we would

suggest that intergroup comparison rather than intragroup comparison should be specified in the results reported in MT trials.

Table 5. Reporting of blinding ($n = 100$)

Who was blinded	Total YES	NA	Pre-C YES	Post-C YES	% Change	P	95% CI
Participants	31%	–	13 (26%)	18 (36%)	10%	0.52	[–28 to 8]
Practitioners	3%	–	2 (4%)	1 (2%)	–2%	0.61	[–4.6 to 8.6]
Outcome evaluators	60%	–	26 (52%)	34 (68%)	16%	0.22	[–34.9 to 2.9]
Co-intervention practitioners	10%	68%	5 (10%)	5 (10%)	–	0.82	[–15.7 to 15.7]

NA, not applicable.

Finally, adverse events were mentioned in 47% of all trials, with no differences between groups. This low rate of reported adverse events is possibly due to no adverse events occurring in the MT trials analyzed. While the scientific literature is consistent in describing MT as a safe intervention [60–62], adverse events have been reported, ranging from catastrophic (cervical artery dissection resulting in a stroke) for SMT to mild, for example, transient muscle soreness or stiffness, considered an expected outcome of treatment [60,63]. The reporting of adverse events should be considered mandatory regardless of their gravity or frequency. However, and although improvement is evident since the CONSORT guidelines became available [64],

for SMT, in particular, the current level of reporting of adverse events can only be deemed inadequate [65].

For our study of randomly selected articles from CONSORT-adherent and non-CONSORT-adherent journals, our findings are in line with those of Riley et al. [27] for only CONSORT-adherent journals. A similar study of chiropractic treatment that explored associations between certain variables and overall reporting quality found that reporting was influenced by year of publication and sample size, but not by journal type, funding source, or positive outcomes [66].

While our results are also consistent with other similar reviews of physical therapies [26,67], they contrast with

Table 6. Reporting of participant flow and follow-up details ($n = 100$)

Total YES	NA	Pre-C yes	Post-C yes	% Change	P	95% CI
Is the number of participants who were randomly assigned indicated?						
100%	–	50 (100%)	50 (100%)	–	–	–
Is the number of participants who received the intended treatment indicated?						
97%	–	48 (96%)	49 (98%)	2%	1.0	[–8.6 to 4.6]
Is compliance with the intended treatment described?						
85%	–	42 (84%)	43 (86%)	2%	1.0	[–16 to 12]
Are missing data/dropouts/losses to follow-up described?						
89%	–	44 (88%)	45 (90%)	2%	1.0	[–14.3 to 10.3]
Are reasons given for missing data/dropouts/losses to follow-up?						
51%	37%	25 (50%)	26 (52%)	2%	0.99	[–21.6 to 17.6]
Is the number of participants analyzed for the primary outcome indicated?						
95%	–	48 (96%)	47 (94%)	–2%	0.36	[–6.5 to 10.5]
Have there been any deviations from the planned protocol?						
5%	30%	2 (4%)	3 (6%)	2%	0.58	[–10.5 to 6.5]
Is the number of therapists/centers given for each intervention?						
34%	–	15 (30%)	19 (38%)	8%	0.53	[–26.5 to 10.5]
Is the number of patients treated by each therapist/center given?						
17%	33%	8 (16%)	9 (18%)	2%	0.83	[–16.7 to 12.7]

NA, not applicable.

positive results of reporting quality found in other fields [22,24,68,69]. This would suggest that the application of the CONSORT guidelines may have a different impact depending on the study field. Although an association between poor methodological quality in design and poor reporting quality is to be expected, results to date and the comments of a number of authors raise questions regarding the use of reporting guidelines and their effectiveness in improving the scientific literature:

4.1. Are the items in the CONSORT guidelines sufficiently clear for manuscript authors?

The availability of resources to enhance understanding of and accessibility to reporting guidelines and their items has been discussed [70,71]. Moreover, specific instructions on how CONSORT should be used by authors are inconsistent across journals and publishers [72]. To the best of our knowledge, there are no specific study surveying authors regarding the clarity of CONSORT checklist items. On the other hand, studies evaluating strategies aiming to help authors prepare more complete trial reports (e.g., WebCONSORT) conclude that more detailed information on how to implement each item within the context of a specific trial is needed [73]. As an example, our study involved a review team comprised of clinical MT experts and researchers with extensive experience in methodological aspects of RCTs. While the pilot run of the reviewers' analysis resulted in substantial agreement, clear differences in criteria arose and needed to be discussed. The use of a structured approach for reporting research [74] or the use of the writing aid tool COBWEB [75] are considered good strategies to help authors improve adherence to reporting guidelines in health research [70]

4.2. For CONSORT-adherent journals, is there a standardized process to evaluate article adherence to the reporting guidelines?

Beyond general recommendations, a mechanism needs to be put in place so that article submission is conditional on the inclusion of the information required by the guidelines [72,76]. Moreover, researchers and peer-reviewers should also receive training on the use of these guidelines [76,77], and editors should incorporate them into the editorial process, as inconsistencies between what authors claimed on submitted checklists and what was actually reported in the published paper have been found [76]. This requirement would not only enhance reporting quality but could also potentially improve the methodological quality of studies.

4.3. Is it possible that the usefulness of CONSORT guidelines depends on the study field? Is the extension for nonpharmacological interventions suitable for all nonpharmacological interventions?

To date, the number of studies pointing to a significant impact of the CONSORT guidelines (or its extensions) on

pharmacological interventions [22,69,78] seems to be greater than that in nonpharmacological interventions [79–81]. The nonpharmacological label may be an umbrella term that covers a wide number and variety of very different interventions. It is plausible to consider that the same set of guidelines may not adequately cover the specific features of different kinds of interventions. For instance, the CONSORT guidelines have had a limited impact on reporting quality in the fields of dentistry and surgery [79–83], while the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [84] have had a positive impact on the quality of clinical trial reporting in acupuncture [85–87], despite some poor results [88–90]. It could be argued that the existence of guidelines or extensions adapted to specific interventions could potentially enhance reporting quality and research methods. However, a new strategy for developing guidelines or extensions should be considered in order to reduce authors' potential workload and to increase adherence [71].

4.4. Strengths and limitations

We acknowledge several limitations in this review. The selected articles may not be representative of the complete MT body of evidence. However, we have tried to minimize possible selection bias by using a random sample of published trials. Furthermore, we searched CENTRAL as the most comprehensive source of trials [29,30], and the most valid one to retrieve trials on physical therapy [31]. Although we initially searched MEDLINE, we realized that this database missed relevant journals in the MT field that are included in CENTRAL.

On the other hand, we did not differentiate between CONSORT-adherent and non-CONSORT-adherent journals in selecting the sample, so this could have an impact on our findings. Also, our sample includes MT RCTs published up to 2015, so our study is not able to assess if the quality of reporting has changed in the last 4 years. For example, taking into account that TIDieR was published in 2014 and that it has been recommended for its use in physical [91] and manual therapies [21], it is reasonable to expect an effect on most recent publications related to intervention descriptions.

We assessed the evolution of reporting in MT trials from a comprehensive approach focusing on relevant issues in MT regarding internal validity, reliability, and the description for the interventions, which are identified as shortcomings in this field. We designed a data extraction form selecting items from standardized reporting guidelines (i.e., CONSORTnpt and TIDieR), and we also included others that were considered relevant by the researchers conducting the study. Some of these aspects have been added to the CONSORTnpt update and indirectly validates our decision.

In relation to the reviewer response options, while strategies were established to minimize differences in criteria, results may have varied among our review group members.

Our reviewers reported some difficulties in determining how to rate some items, in some cases due to a lack of/deficient information in the articles themselves and, in other cases, due to the lack of response options—binary in some cases (YES/NO) and in other cases, including NOT APPLICABLE. The fact that a NOT CLEAR option was not included for the YES/NO statements left the reviewers having to opt for either response in cases of doubt.

5. Conclusion

Reporting guidelines aim to help researchers better describe their research to ultimately improve methodological transparency and thus allowing replication and bias assessment. Regarding RCTs, authors are required to present their research in compliance with CONSORT guidelines and most peer-reviewed journals that endorse CONSORT. However, several years after the publication of CONSORT guidelines and extensions, the quality of reporting continues to be very uneven. Our findings suggest that trials in MT show poor reporting even after the availability of standardized guidelines. Adherence to these reporting guidelines should be a mandatory submission requirement for MT trialists. In relation to nonpharmacological interventions, the development of extensions related to specific interventions could potentially improve the quality of reporting.

CRedit authorship contribution statement

Gerard Alvarez: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. **Ivan Solà:** Supervision, Investigation, Writing - review & editing. **Mercè Sitjà-Rabert:** Investigation, Writing - review & editing. **Azahara Fort-Vanmeerhaeghe:** Investigation, Writing - review & editing. **Ignasi Gich:** Formal analysis, Writing - review & editing. **Carles Fernández:** Investigation, Writing - review & editing. **Xavier Bonfill:** Supervision, Writing - review & editing. **Gerard Urrútia:** Conceptualization, Methodology, Supervision, Writing - review & editing.

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Supplementary data

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