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

Gerard Alvarez,[a,b] Ivan Solà,[a,c] Mercè Sitjà-Rabert,[d,e] Azahara Fort-Vanmeerhaeghe,[d,f] Ignasi Gich,[c,g] Carles Fernández,[d,e] Xavier Bonfill,[a,c] Gerard Urrutia[a,c]

Affiliation:

a. Iberoamerican Cochrane Centre – Biomedical Research Institute Sant Pau, IIB Sant Pau, Barcelona, Spain
b. Foundation Centre for Osteopathic Medicine Collaboration. Spain National Centre, Barcelona, Spain
c. CIBER Epidemiología y Salud Pública (CIBERESP), Spain
d. School of Health Science (FCS) Blanquerna, Ramon Llull University, Barcelona, Spain
e. Global Research on Wellbeing (GRoW) Research Group, Ramon Llull University, Barcelona, Spain
f. Faculty of Psychology, Education Sciences and Sport (FPCEE) Blanquerna, Ramon Llull University, Barcelona, Spain
g. Clinical Epidemiology and Public Health Department, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

Contact author: Gerard Alvarez: gerardalv@gmail.com
+34 620 214 206
Iberoamerican Cochrane Center
C. Sant Antoni Maria Claret 167
Pavelló 18 | Planta 0
08025 Barcelona | Catalunya | Spain

Gerard Alvarez (gerardalv@gmail.com)
Iberoamerican Cochrane Centre
Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain
Foundation Centre for Osteopathic Medicine Collaboration. Spain National Centre, Barcelona, Spain

Ivan Solà (ISola@santpau.cat)
Iberoamerican Cochrane Center
Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain
CIBER Epidemiología y Salud Pública (CIBERESP), Spain

Mercè Sitjà (mercesr@blanquerna.url.edu)
School of Health Science (FCS) Blanquerna, Ramon Llull University, Barcelona, Spain
Global Research on Wellbeing (GRoW) Research Group, Ramon Llull University, Barcelona, Spain

Azahara Fort Vanmeerhaeghe (azaharafv@blanquerna.url.edu)
School of Health Science (FCS) Blanquerna, Ramon Llull University, Barcelona, Spain
Faculty of Psychology, Education Sciences and Sport (FPCEE) Blanquerna, Ramon Llull University, Barcelona, Spain

Ignasi Gich (IGichs@santpau.cat)
CIBER Epidemiología y Salud Pública (CIBERESP), Spain
Clinical Epidemiology and Public Health Department, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

Carles Fernández Jané (**carlesfj@blanquerna.url.edu**)
School of Health Science (FCS) Blanquerna, Ramon Llull University, Barcelona, Spain
Global Research on Wellbeing (GRoW) Research Group, Ramon Llull University, Barcelona, Spain

Xavier Bonfill (XBonfill@santpau.cat)
Iberoamerican Cochrane Centre
Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain
CIBER Epidemiología y Salud Pública (CIBERESP), Spain

Gerard Urrutia (GUrrutia@santpau.cat)
Iberoamerican Cochrane Centre
Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain
CIBER Epidemiología y Salud Pública (CIBERESP), Spain

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 availability of standardized guidelines.

Keywords: CONSORT, manual therapy, reporting, quality, guidelines, nonpharmacological

What is new?

- Manual therapy trials show poor reporting quality
- The implementation of reporting guidelines could have a minimal impact on this field
- Guidelines specifically adapted to each kind of non-pharmacological intervention could potentially enhance reporting quality and research methods.

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]. 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, despite a growing interest in MT, there is an important lack of quality studies and of 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 non-pharmacological 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 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. 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 towards implementation of reporting guidelines in order to enhance the quality of scientific reports in this field[25]. However, recent research shows that, despite a 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 non-pharmacological 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-CONSORT group (pre-C) was composed of articles published between 2000 and 2008, and the post-CONSORT 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 on **Appendix 1**.

2.3 Sample size calculation

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 non-parametric analysis was performed using the Mann-Whitney U test. We assumed an α=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.

2.5 Data analysis

The analysis was performed using IBM-SPSS Statistics for Windows, Version 25.0. (Armonk, NY: 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 1519 pre-C and 1728 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 multicenter 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.

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, counterstrain 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, 10 articles used more than one control (9 articles with 2 controls and 1 article with 3 controls); and in the post-C group, 8 articles used more than one control (6 articles with 2 controls and 2 articles with 3 controls).

Table 2 summarizes details of 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, long-term follow-up 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 follow-up, 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 results of an overall comparison regarding adequately reported items. The mean (SD) in the pre-C group versus the post-C group was 18.87 (4.93) versus 19.98 (4.94), with no statistically significant overall difference between the 2 groups (p=0.26 [-3.06 to 0.85]). Regarding internal validity and reliability, only 2 items showed significant differences between the 2 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 2 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 two 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 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 on **Appendix 3.**

4. DISCUSSION

We conducted a study to assess 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 (i.e. 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 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 quality and reporting of MT research[33–35].

Our results show that despite some improvements in participant, practitioner and setting descriptions in trials of 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≥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 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, yet 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 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 which may point to an improvement in this particular aspect.

Since non-pharmacological 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 follow-up. Trialists therefore need to be aware of the fact that a small or underpowered sample in an RCT with long-term follow-up can potentially be affected by attrition bias. Information on attrition and its impact on baseline imbalances has 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 non-pharmacological 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 non-pharmacological 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 between the 2 study groups. As shown in **Table 6**, the number of randomly allocated participants and information on missing data, dropouts and losses to follow-up 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 result analysis should apply the same pragmatic approach, i.e. 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 reasons above, 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 PEDro 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.

"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 inter-group comparison rather than intra-group comparison should be specified in the results reported in MT trials.

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 trails 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 stroke) for SMT to mild, e.g. 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 an 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 positive results of reporting quality found in other fields[22,24,68,69]. This would suggest that 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 is 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 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 non-pharmacological interventions suitable for all non-pharmacological 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 non-pharmacological interventions[79–81]. The non-pharmacological 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 four years. For example, taking into an 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 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 availability of standardized guidelines. Adherence to these reporting guidelines should be a mandatory submission requirement for MT trialists. In relation to non-pharmacological interventions, the development of extensions related to specific interventions could potentially improve the quality of reporting.

ACKNOWLEDGEMENTS

The authors wish to acknowledge Ms. Victoria Leo for her contribution in improving the manuscript.

FUNDING SOURCES

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

REFERENCES

1. French HP, Brennan A, White B, Cusack T. Manual therapy for osteoarthritis of the hip or knee - A systematic review. *Man Ther*. 2011;16(2):109-117. doi:10.1016/j.math.2010.10.011
2. Rivett DA. Editorial - Manual therapy cults. *Man Ther*. 1999;4(3):125-126. doi:10.1054/math.1999.0195
3. Bialosky JE, Bishop MD, Price DD, Robinson ME, George SZ. The mechanisms of manual therapy in the treatment of musculoskeletal pain: A comprehensive model. *Man Ther*. 2009. doi:10.1016/j.math.2008.09.001
4. Voogt L, de Vries J, Meeus M, Struyf F, Meuffels D, Nijs J. Analgesic effects of manual therapy in patients with musculoskeletal pain: A systematic review. *Man Ther*. 2015;20(2):250-256. doi:10.1016/j.math.2014.09.001
5. Clar C, Tsertsvadze A, Court R, Hundt G, Clarke A, Sutcliffe P. Clinical effectiveness of manual therapy for the management of musculoskeletal and non-musculoskeletal conditions: systematic review and update of UK evidence report. *Chiropr Man Therap*. 2014;22(1):12. doi:10.1186/2045-709X-22-12
6. Hondras MA, Linde K, Jones AP. Manual therapy for asthma. *Cochrane Database Syst Rev*. 2002;(2). doi:10.1002/14651858.CD001002
7. Bokarius A V, Bokarius V. Evidence-based review of manual therapy efficacy in treatment of chronic musculoskeletal pain. *Pain Pract*. 2010;10(5):451-458. doi:10.1111/j.1533-2500.2010.00377.x
8. Orrock PJ, Myers SP. Osteopathic intervention in chronic non-specific low back pain: a systematic review. *BMC Musculoskelet Disord*. 2013;14:129. doi:10.1186/1471-2474-14-129
9. Page MJ, Green S, Kramer S, et al. Manual therapy and exercise for adhesive capsulitis. *Cochrane Database Syst Rev*. 2014;(8):1-225. doi:10.1002/14651858.CD011275.www.cochranelibrary.com
10. Peek AL, Miller C, Heneghan NR. Thoracic manual therapy in the management of non-specific shoulder pain: a systematic review. *dx.doi.org*. 2015;23(4):176-187. doi:10.1179/2042618615Y.0000000003
11. Cicchitti L, Martelli M, Cerritelli F. Chronic inflammatory disease and osteopathy: A systematic review. PLoS One. 2015. doi:10.1371/journal.pone.0121327

12. Ruffini N, D'Alessandro G, Cardinali L, Frondaroli F, Cerritelli F. Osteopathic manipulative treatment in gynecology and obstetrics: A systematic review. *Complement Ther Med*. 2016. doi:10.1016/j.ctim.2016.03.005
13. Cerritelli F, Ruffini N, Lacorte E, Vanacore N. Osteopathic manipulative treatment in neurological diseases: Systematic review of the literature. *J Neurol Sci*. 2016. doi:10.1016/j.jns.2016.08.062
14. Cerritelli F, Lacorte E, Ruffini N, Vanacore N. Osteopathy for primary headache patients: a systematic review. *J Pain Res*. 2017. doi:10.2147/JPR.S130501
15. Bird L, Arthur A, Cox K. "Did the trial kill the intervention?" experiences from the development, implementation and evaluation of a complex intervention. *BMC Med Res Methodol*. 2011;11. doi:10.1186/1471-2288-11-24
16. Clark AM. What are the components of complex interventions in healthcare? Theorizing approaches to parts, powers and the whole intervention. *Soc Sci Med*. 2013;93:185-193. doi:10.1016/j.socscimed.2012.03.035
17. Bennell KL, Egerton T, Pua Y-H, Abbott JH, Sims K, Buchbinder R. Building the Rationale and Structure for a Complex Physical Therapy Intervention Within the Context of a Clinical Trial: A Multimodal Individualized Treatment for Patients With Hip Osteoarthritis. *Phys Ther*. 2011;91(10):1525-1541. doi:10.2522/ptj.20100430
18. Hawe P, Shiell A, Riley T. Complex interventions : how " out of control " can a randomised controlled trial be ? 2004;(June):1561-1563.
19. Dieppe P. Complex interventions. *Musculoskeletal Care*. 2004;2(3):180-186. doi:10.1002/msc.69
20. Coronado RA, Bialosky JE. Manual physical therapy for chronic pain: the complex whole is greater than the sum of its parts. *J Man Manip Ther*. 2017;25(3):115-117. doi:10.1080/10669817.2017.1309344
21. Alvarez G, Cerritelli F, Urrutia G. Using the template for intervention description and replication (TIDieR) as a tool for improving the design and reporting of manual therapy interventions. *Man Ther*. 2016;24:85-89.
22. Plint AC, Moher D, Morrison A, et al. Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Med J Aust*. 2006;185(5):263-267. doi:pli11098_fm [pii]
23. Reveiz L, Chapman E, Asial S, Munoz S, Bonfill X, Alonso-Coello P. Risk of bias of randomized trials over time. *J Clin Epidemiol*. 2015;68(9):1036-1045. doi:10.1016/j.jclinepi.2014.06.001
24. Dechartres A, Charles P, Hopewell S, Ravaud P, Altman DG. Reviews assessing the quality or the reporting of randomized controlled trials are increasing over time but raised questions about how quality is assessed. *J Clin Epidemiol*. 2011;64(2):136-144. doi:10.1016/j.jclinepi.2010.04.015

25. Chan L, Heinemann AW, Roberts J. Elevating the quality of disability and rehabilitation research: Mandatory use of the reporting guidelines. *Am J Occup Ther*. 2014;68(2):127-129. doi:10.5014/ajot.2014.682004
26. Gonzalez GZ, Moseley AM, Maher CG, Nascimento DP, Costa L i ola da CMLOL da CM, Costa L i ola da CMLOL da CM. Methodologic Quality and Statistical Reporting of Physical Therapy Randomized Controlled Trials Relevant to Musculoskeletal Conditions. *Arch Phys Med Rehabil*. 2018;99(1):129-136. doi:10.1016/j.apmr.2017.08.485
27. Riley SP, Swanson B, Brismée J-M, Sawyer SF. A systematic review of orthopaedic manual therapy randomized clinical trials quality. *J Man Manip Ther*. 2016;24(5):241-252. doi:10.1080/10669817.2015.1119372
28. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: Explanation and elaboration. *Ann Intern Med*. 2008. doi:10.7326/0003-4819-148-4-200802190-00008
29. Egger M, Smith GD. Bias in location and selection of studies. *Br Med J*. 1998;316(7124):61-66.
30. Higgins J, Green S. *Cochrane Handbook for Systematic Reviews of Interventions*.; 2011. doi:http://handbook.cochrane.org/
31. Michaleff ZA, Costa LOP, Moseley AM, et al. CENTRAL, PEDro, PubMed, and EMBASE Are the Most Comprehensive Databases Indexing Randomized Controlled Trials of Physical Therapy Interventions. *Phys Ther*. 2011;91(2):190-197.
32. Pillastrini P, Vanti C, Curti S, et al. Using PubMed search strings for efficient retrieval of manual therapy research literature. *J Manipulative Physiol Ther*. 2015. doi:10.1016/j.jmpt.2014.11.005
33. Koes BW. How to evaluate manual therapy: Value and pitfalls of randomized clinical trials. *Man Ther*. 2004;9(4):183-184. doi:10.1016/j.math.2004.04.002
34. Wade DT, Smeets RJEM, Verbunt JA. Research in rehabilitation medicine: Methodological challenges. *J Clin Epidemiol*. 2010;63(7):699-704. doi:10.1016/j.jclinepi.2009.07.010
35. Arienti C, Armijo-Olivo S, Evidence SMBMJ, 2019. 60 Methodological issues in rehabilitation research: a scoping review. *search.proquest.com*.
36. Hoffmann TC, Glasziou PP, Boutron I, et al. Better Reporting of Interventions: Template for Intervention Description and Replication (TIDieR) Checklist and Guide. *Gesundheitswesen*. 2016. doi:10.1055/s-0041-111066
37. Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 2006. doi:10.2307/2529310
38. Boutron I, Altman DG, Moher D, et al. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. *Ann Intern Med*. 2017;167(1):40-47. doi:10.7326/M17-0046

39. Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Lancet (London, England)*. 2009;374(9683):86-89.
40. Glasziou P, Altman DG, Bossuyt P, et al. Reducing waste from incomplete or unusable reports of biomedical research. *Lancet (London, England)*. 2014;383(9913):267-276.
41. Henschke N, Kuijpers T, Rubinstein SM, et al. Trends over time in the size and quality of randomised controlled trials of interventions for chronic low-back pain. *Eur Spine J*. 2012;21(3):375-381.
42. Rubinstein SM, Van Eekelen R, Oosterhuis T, De Boer MR, Ostelo RWJGJG, Van Tulder MW. The risk of bias and sample size of trials of spinal manipulative therapy for low back and neck pain: Analysis and recommendations. *J Manipulative Physiol Ther*. 2014;37(8):523-541. doi:10.1016/j.jmpt.2014.07.007
43. Hassett AL, Williams DA. Non-pharmacological treatment of chronic widespread musculoskeletal pain. *Best Pract Res Clin Rheumatol*. 2011. doi:10.1016/j.berh.2011.01.005
44. Reimold AM, Chandran V. Nonpharmacologic therapies in spondyloarthritis. *Best Pract Res Clin Rheumatol*. 2014. doi:10.1016/j.berh.2014.10.003
45. Chang K-L, Fillingim R, Hurley RW, Schmidt S. Chronic pain management: nonpharmacological therapies for chronic pain. *FP Essent*. 2015;432:21-26.
46. Hewitt CE, Kumaravel B, Dumville JC, Torgerson DJ. Assessing the impact of attrition in randomized controlled trials. *J Clin Epidemiol*. 2010;63(11):1264-1270. doi:10.1016/j.jclinepi.2010.01.010
47. Boutron I, Guittet L, Estellat C, Moher D, Hróbjartsson A, Ravaud P. Reporting methods of blinding in randomized trials assessing nonpharmacological treatments. *PLoS Med*. 2007;4(2):0370-0380. doi:10.1371/journal.pmed.0040061
48. Fregni F, Imamura M, Chien HF, et al. Challenges and recommendations for placebo controls in randomized trials in physical and rehabilitation medicine: A report of the international placebo symposium working group. *Am J Phys Med Rehabil*. 2010. doi:10.1097/PHM.0b013e3181bc0bbd
49. Villamar MF, Contreras VS, Kuntz RE, Fregni F. The reporting of blinding in physical medicine and rehabilitation randomized controlled trials: A systematic review. *J Rehabil Med*. 2013;45(1):6-13. doi:10.2340/16501977-1071
50. Hancock MJ, Maher CG, Latimer J, McAuley JH. Selecting an appropriate placebo for a trial of spinal manipulative therapy. *Aust J Physiother*. 2006;52(2):135-138. doi:10.1016/S0004-9514(06)70049-6
51. Cerritelli F, Verzella M, Cicchitti L, D'Alessandro G, Vanacore N. The paradox of sham therapy and placebo effect in osteopathy A systematic review. *Med (United States)*. 2016;95(35). doi:10.1097/MD.0000000000004728
52. Di Blasi Z, Harkness E, Ernst E, Georgiou A, Kleijnen J. Influence of context effects on health outcomes: a systematic review. Lancet. 2001;357(9258):757-762.

53. Di Blasi Z, Kleijnen J. Context effects. Powerful therapies or methodological bias? *Eval Health Prof*. 2003;26(2):166-179.
54. Rossettini G, Carlino E, Testa M. Clinical relevance of contextual factors as triggers of placebo and nocebo effects in musculoskeletal pain. *BMC Musculoskelet Disord*. 2018;19(1):27.
55. Hróbjartsson A, Forfang E, Haahr MT, Als-Nielsen B, Brorson S. Blinded trials taken to the test: An analysis of randomized clinical trials that report tests for the success of blinding. *Int J Epidemiol*. 2007;36(3):654-663. doi:10.1093/ije/dym020
56. Kolahi J, Bang H, Park J. Towards a proposal for assessment of blinding success in clinical trials: up-to-date review. *Community Dent Oral Epidemiol*. 2009;37(6):477-484.
57. Moseley AM, Herbert RD, Maher CG, Sherrington C, Elkins MR. Reported quality of randomized controlled trials of physiotherapy interventions has improved over time. *J Clin Epidemiol*. 2011;64(6):594-601. doi:10.1016/j.jclinepi.2010.08.009
58. Elkins MR, Moseley AM. Intention-to-treat analysis. *J Physiother*. 2015;61(3):165-167. doi:10.1016/j.jphys.2015.05.013
59. Sedgwick P. Intention to treat analysis versus per protocol analysis of trial data. *BMJ*. 2015;350(February):1-2. doi:10.1136/bmj.h681
60. Carnes D, Mars TS, Mullinger B, Froud R, Underwood M. Adverse events and manual therapy: A systematic review. *Man Ther*. 2010. doi:10.1016/j.math.2009.12.006
61. Paanalahti K, Holm LW, Nordin M, Asker M, Lyander J, Skillgate E. Adverse events after manual therapy among patients seeking care for neck and/or back pain: A randomized controlled trial. *BMC Musculoskelet Disord*. 2014. doi:10.1186/1471-2474-15-77
62. Todd AJ, Carroll MT, Robinson A, Mitchell EKL. Adverse Events Due to Chiropractic and Other Manual Therapies for Infants and Children: A Review of the Literature. *J Manipulative Physiol Ther*. 2015. doi:10.1016/j.jmpt.2014.09.008
63. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: An exploratory qualitative analysis of the patient perspective. *Man Ther*. 2011. doi:10.1016/j.math.2011.02.001
64. Gorrell LM, Brown B, Lystad RP, Engel RM. Predictive factors for reporting adverse events following spinal manipulation in randomized clinical trials - secondary analysis of a systematic review. *Musculoskelet Sci Pract*. 2017;30:34-41. doi:10.1016/j.msksp.2017.05.002
65. Gorrell LM, Engel RM, Brown B, Lystad RP. The reporting of adverse events following spinal manipulation in randomized clinical trials—a systematic review. *Spine J*. 2016;16(9):1143-1151. doi:10.1016/j.spinee.2016.05.018
66. Karpouzis F, Bonello R, Pribicevic M, Kalamir A, Brown BT. Quality of reporting of randomised controlled trials in chiropractic using the CONSORT checklist. *Chiropr Man Therap. May 2016:1-13.*

67. Moseley AM, Elkins MR, Janer-Duncan L, Hush JM. The quality of reports of randomized controlled trials varies between subdisciplines of physiotherapy. *Physiother Canada*. 2014;66(1):36-43. doi:10.3138/ptc.2012-68
68. Kane RL, Wang J, Garrard J. Reporting in randomized clinical trials improved after adoption of the CONSORT statement. *J Clin Epidemiol*. 2007;60(3):241-249. doi:10.1016/j.jclinepi.2006.06.016
69. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane reviewa. *Syst Rev*. 2012;1(1):1. doi:10.1186/2046-4053-1-60
70. Blanco D, Altman D, Moher D, Boutron I, Kirkham JJ, Cobo E. Scoping review on interventions to improve adherence to reporting guidelines in health research. *BMJ Open*. 2019;9(5):e026589--12.
71. Ghosn L, Boutron I, Ravaud P. Consolidated Standards of Reporting Trials (CONSORT) extensions covered most types of randomized controlled trials, but the potential workload for authors was high. *J Clin Epidemiol*. 2019;113:168-175.
72. Shamseer L, Hopewell S, Altman DG, Moher D, Schulz KF. Update on the endorsement of CONSORT by high impact factor journals: a survey of journal "Instructions to Authors" in 2014. *Trials*. 2016;17(1):301.
73. Hopewell S, Boutron I, Altman DG, et al. Impact of a web-based tool (WebCONSORT) to improve the reporting of randomised trials: results of a randomised controlled trial. *BMC Med*. 2016;14(1):199.
74. Pandis N, Turpin DL. Enhancing CONSORT compliance for improved reporting of randomized controlled trials. *Am J Orthod Dentofac Orthop*. 2014. doi:10.1016/j.ajodo.2013.11.005
75. Barnes C, Boutron I, Giraudeau B, Porcher R, Altman DG, Ravaud P. Impact of an online writing aid tool for writing a randomized trial report: The COBWEB (Consort-based WEB tool) randomized controlled trial. *BMC Med*. 2015. doi:10.1186/s12916-015-0460-y
76. Blanco D, Biggane AM, Cobo E. Are CONSORT checklists submitted by authors adequately reflecting what information is actually reported in published papers? January 2018:1-4.
77. Moher D, Altman DG. Four Proposals to Help Improve the Medical Research Literature. *PLoS Med*. 2015. doi:10.1371/journal.pmed.1001864
78. Moher D, Jones A, Lepage L. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. *JAMA*. 2001;285(15): 1992-1995.

79. Gray R, Sullivan M, Altman DG, Gordon-Weeks AN. Adherence of trials of operative intervention to the CONSORT statement extension for nonpharmacological treatments: A comparative before and after study. Ann R Coll Surg Engl. 2012;94(6):388-394. doi:10.1308/003588412X13171221592339
80. Nagendran M, Harding D, Teo W, et al. Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacological treatments (NPT): A cross-sectional study. *BMJ Open*. 2013;3(12):1-7. doi:10.1136/bmjopen-2013-003898
81. Sarkis-Onofre R, Poletto-Neto V, Cenci MS, Pereira-Cenci T, Moher D. Impact of the CONSORT Statement endorsement in the completeness of reporting of randomized clinical trials in restorative dentistry. *J Dent*. 2017;58:54-59. doi:10.1016/j.jdent.2017.01.009
82. Agha R, Cooper D, Muir G. The reporting quality of randomised controlled trials in surgery: a systematic review. *Int J Surg*. 2007;5(6):413-422. doi:10.1016/j.ijsu.2007.06.002
83. Savithra P, Nagesh LS. Have CONSORT guidelines improved the quality of reporting of randomised controlled trials published in public health dentistry journals? *Oral Health Prev Dent*. 2013;11(2):95-103. doi:10.3290/j.ohpd.a29359
84. Macpherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT Statement. 2010;7(6). doi:10.1371/journal.pmed.1000261
85. Asher GN, Motsinger-Reif AA, Jonas DE, Viera AJ. Quality of reporting on randomised controlled trials of auriculotherapy for pain. *Acupunct Med*. 2011;29(2):122-126.
86. Ma B, Chen Z min, Xu J ke, et al. Do the CONSORT and STRICTA Checklists Improve the Reporting Quality of Acupuncture and Moxibustion Randomized Controlled Trials Published in Chinese Journals? A Systematic Review and Analysis of Trends. *PLoS One*. 2016;11(1):e0147244. doi:10.1371/journal.pone.0147244
87. Svenkerud S, MacPherson H. The impact of STRICTA and CONSORT on reporting of randomised control trials of acupuncture: a systematic methodological evaluation. *Acupunct Med*. September 2018. doi:10.1136/acupmed-2017-011519
88. Kim KH, Kang JW, Lee MS, Lee J-D. Assessment of the quality of reporting in randomised controlled trials of acupuncture in the Korean literature using the CONSORT statement and STRICTA guidelines. *BMJ Open*. 2014;4(7):e005068--e005068.
89. Zeng J, Lin G, Li L, Lu L, Chen C, Lu L. Assessment of reporting quality in randomised controlled trials of acupuncture for post-stroke rehabilitation using the CONSORT statement and STRICTA guidelines. *Acupunct Med*. 2017;35(2):100-106.
90. Jia P, Tang L, Yu J, Liu J, Kang D, Sun X. The quality of reporting in randomized controlled trials of acupuncture for knee osteoarthritis: A cross-sectional survey. *PLoS One*. 2018;13(4):e0195652--14.
91. Yamato TP, Maher CG, Saragiotto BT, Moseley AM, Hoffmann TC, Elkins MR. The TIDieR checklist will benefit the physiotherapy profession. *J Physiother*. 2016;62(2):57-58.

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

Experimental interventions			
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	N	Pre-C	Post-C
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**

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

	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
Post-operative 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**

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	60%	-	26 (52%)	34 (68%)	16%	0.22	[-34.9 to 2.9]

Description	% Total YES	NA	Pre-C YES	Post-C YES	% change	p	95% CI
indicated							
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***	**[-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]
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]

Description	% Total YES	NA	Pre-C YES	Post-C YES	% change	p	95% CI
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***	**[-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

*P<0.05

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***	**[-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]

Description	% Total YES	NA	Pre-C YES	Post-C YES	% change	p	95% CI
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

*P<0.05

Table 5: Reporting of blinding (n=100)

	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

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

Fig 1: Study selection flowchart.

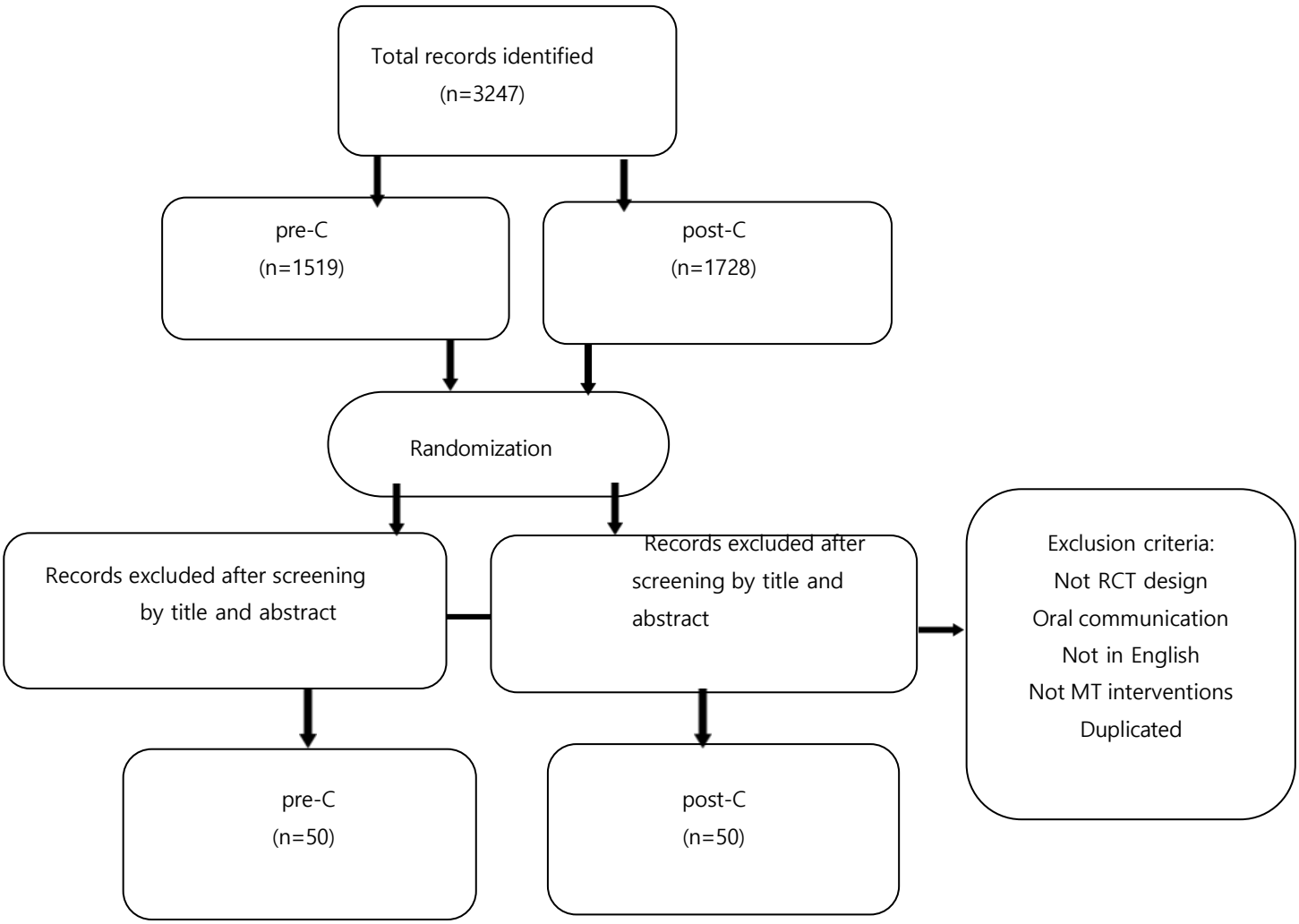
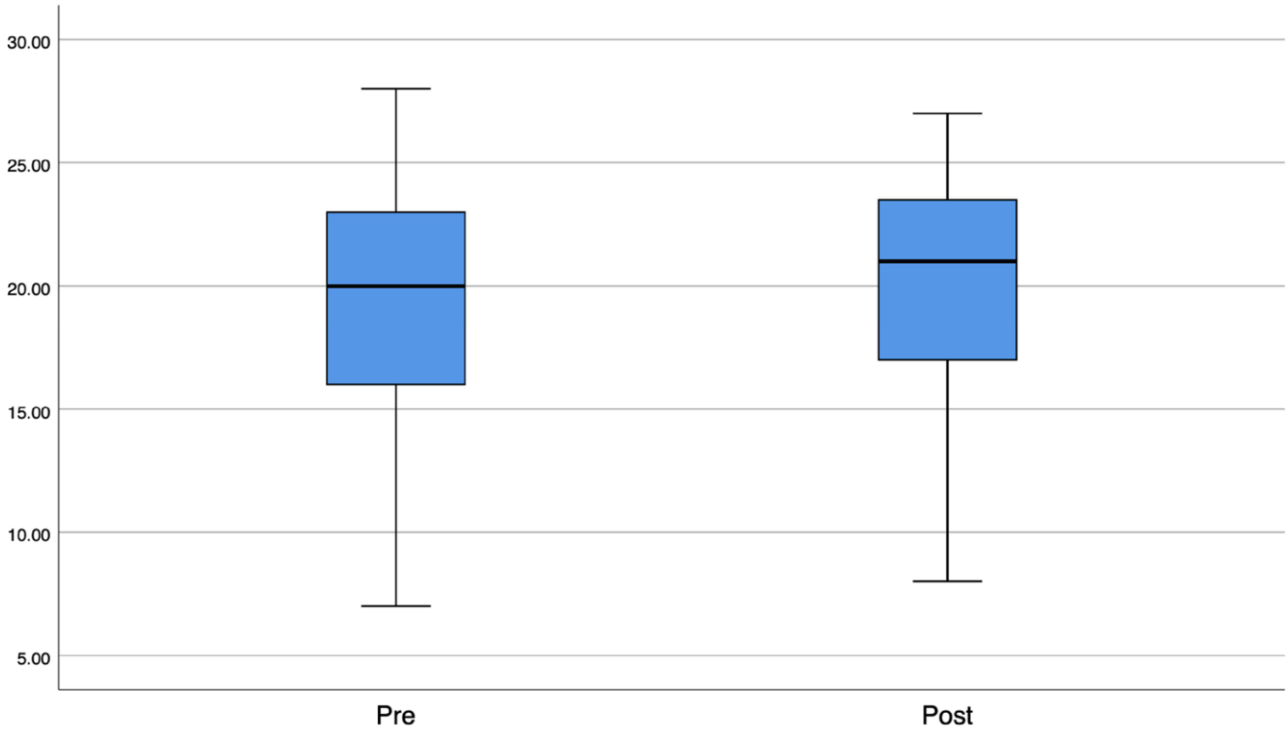


Fig 2: Overall comparison for items adequately reported by the pre-C and post-C groups.



AUTHOR STATEMENT

GA conceptualized and designed the study. GA and GU were responsible to create the first version of the data extraction form and IS, MS, AF, CF and GU piloted the form and contributed to reach the final version. IS was responsible of the search strategy and articles retrieval. IS, MS, AF, CF and GU were involved in the data extraction process forming pairs with GA. IG was responsible of data analysis. GA provide the first manuscript draft which received critical revision by GU, IS and XB. All authors read and approved the final manuscript.

The present study is part of the PhD thesis of Gerard Alvarez. If the manuscript is deemed appropriate for his publication and as a requirement of the university I would appreciate that the following statement could be included in the author's information:

"Gerard Alvarez is a PhD student on Biomedical Research Methodology and Public Health in the Medical Department of the Universitat Autònoma de Barcelona. Barcelona, Spain"

The author also wants to state that, before submission, the present manuscript has been revised by a professional editing service to ensure quality and adherence to JCE standards

Conflict of Interest

The authors declare that they have no competing interests.