# Quality of Reporting of Randomized Controlled Trials in Chiropractic using the CONSORT Checklist: A protocol for a review

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## ABSTRACT

**Background:** Despite the introduction of the CONSORT checklist, the quality of reporting of randomized controlled trials (RCTs) within the biomedical literature has been described as suboptimal, with a need for improvement, while that of chiropractic trials remains unexamined.
**Aims**: The aim of this protocol is to develop a tool to assess the overall reporting quality of published chiropractic RCTs using standardised guidelines (i.e. CONSORT), to identify key methodological items that safeguard against biases and to identify predictors of better reporting quality.
**Methods/Design:** A search of RCTs published in English from 2005 - 2014 will be performed in the international clinical trial registers, PubMed and the Cochrane library using keywords and *Medical Subject Headings* (MeSH). Trials will be included if they involve high-velocity low-amplitude spinal or extremity manipulation and are conducted by a chiropractor or within a chiropractic department/institution. RCTs meeting inclusion criteria will be assessed using a customised 39-point rating tool, designed by the authors. The customised tool will be based on the CONSORT 2010 and CONSORT for Non-Pharmacological Treatments statements. Furthermore, each RCT will be assessed according to 4 key methodological items (KMIS); allocation concealment; blinding of participants; blinding of assessors; and the use of intention-to-treat analysis (ITT). Predictors that will be chosen for the study, will be identified in the medical literature as influencing the reporting quality of RCTs such as: industry funding, positive findings, sample size, year of publication and journal type. A multiple regression analyses will be used to explore associations between the outcome, overall quality of reporting score (OQRS) and the predictor variables.
**Discussion:** The results of this study will provide an OQRS in chiropractic RCTs over the last decade. It will provide an individual score for each item of the CONSORT 2010 and CONSORT for Non-Pharmacological Treatments checklists, as well as key methodological items. Furthermore, the study will provide a list of predictors for improved overall quality of reporting of chiropractic RCTs.

**Trial Registry: N/A**

**Ethics Approval:** Murdoch University, Research Ethics and Integrity Office: Ethics #2014/119.

Keywords**:** Manipulation, Chiropractic; Chiropractic; Manipulation; Spinal Manipulative Therapy; Spine; Musculoskeletal; Quality of Reporting; Randomized Controlled Trials; The CONSORT Statement [Chiropr J Australia 2016;44(1):17-32]

## INTRODUCTION

The integrity of best practice guidelines and policies emerging from meta-analyses of RCTs is dependent upon good quality of reporting within the literature.(1-4) Recent reviews of the medical literature suggest that it has been suboptimal (5-9), and requires improvement.(10-14) The original CONSORT (Consolidated Standards for Reporting of Trials) statement (4) and subsequent revisions (15,16) were developed to remedy this situation.CONSORT has been adapted to provide guidelines for: cluster trials (17); non-inferiority and equivalence randomized trials (18); pragmatic trials (19); herbal interventions (20); non-pharmacologic treatment trials (21); acupuncture trials (22); patient-reported outcomes (23); harms data (24); and conference abstracts. (25) To date, there has been no chiropractic-specific CONSORT modification, with researchers generally adopting and interpreting any of the various published versions in an ad-hoc manner.

While the biomedical literature has reported methodological quality ranging from poor to moderate, (26-30) no data exists on chiropractic reporting quality. The closest studies to date relate specifically to spinal manipulative therapy (SMT) for low back pain (LBP) (31) and LBP and neck pain. (32) Both concluded that reporting quality has improved over the years. (31,32)

The rapidly expanding research base within the chiropractic field would be well served by a customised CONSORT guideline to aid researchers in improving the quality of their reporting and to incorporate known key methodological items that safeguard against bias into their reporting protocols. Therefore, the aim of this protocol is to develop a tool to assess the overall reporting quality of published chiropractic RCTs using standardised guidelines.

Key aims of this protocol paper:

- To develop a customized CONSORT tool and scoring procedure, based on the CONSORT Statement and the extension document for Non-Pharmacologic Treatment Interventions, in order to assess the overall quality of reporting score (OQRS) of RCTs in chiropractic.

- To plan a review project of the Chiropractic RCT literature in order to assess chiropractic overall quality of reporting (OQR)
    - To establish inclusion and exclusion criteria for such a project.
    - To identify suitable data sources of chiropractic RCTs, establish extraction and assessment methods.
    - To plan an assessment of KMIS that minimise bias, such as: allocation concealment, blinding, and use of intention-to-treat analysis (ITT) based on the CONSORT statements
    - To draw upon the existing medical literature and identify factors likely to be associated with better OQR in chiropractic trials
        - Select an appropriate set of predictor variables

- To determine a suitable statistical analysis of the data

## METHODS/DESIGN

### Objectives of Review

- To assess the overall quality of reporting of RCTs in chiropractic using a customized CONSORT tool.
- To assess the inclusion of key methodological items (KMIS) in chiropractic RCTs, such as: allocation concealment, blinding of participants and assessors, and use of intention-to-treat analysis (ITT).
- To identify the factors that may contribute to higher quality of reporting.

### Hypothesis Generated

RCTs with industry funding, positive findings, larger sample sizes, later year of publication and publication in non-chiropractic journals will be associated with better quality of reporting.

### Data Sources and Extraction

A search of 10 international clinical trial registries from January 2005 to July 2014 to identify publications involving chiropractic RCTs (Figure 1) will be conducted. In addition, 2 electronic databases (PubMed and the Cochrane Database of Systematic Reviews) will also be searched.

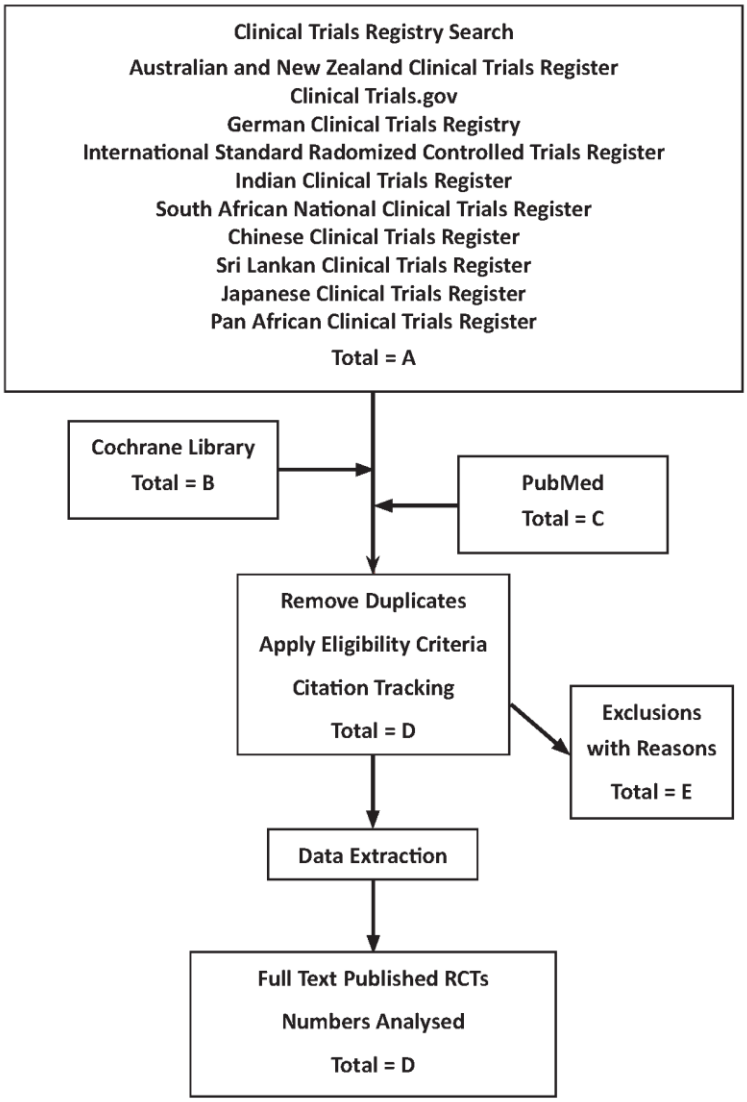
Forward and reverse citation tracking will be performed on all articles that meet the inclusion criteria. Grey literature will be excluded. The key words and *Medical Subject Headings* (MeSH) that will be used are: *spine, lower extremity, upper extremity, musculoskeletal manipulations, manipulation, chiropractic, spinal manipulative therapy*, and *chiropractic*. An example of the search strategy used for the PubMed database will be provided (Figure 2). An initial screening of the title and abstracts of the search results will be performed by two reviewers (FK and BB) to remove duplicates.

Data extraction from the articles that meet the inclusion criteria will be conducted by all authors independently. Any disagreements between authors will be resolved by a third assessor who will arbitrate over any differences. A log of excluded articles will also be created along with the reason/s for the exclusion. A standardised electronic spreadsheet has been created for each author to record the extracted data. The details extracted will include: author(s) name(s); title; clinical trial registration; journal name; year of publication; cohort; sample size; condition studied; whether it has a positive finding; whether it has industry funding; and the name of funding source. The characteristics of included studies will be reported in table format and described in a narrative synthesis.

The articles remaining after the initial screening will be obtained in full text and assessed by at least two authors according to eligibility criteria. Discrepancies

will be resolved via consensus.

**Figure 1:** *Flow diagram of RCT selection process*



| |
|---|
| #1 “spine” [MeSH] |
| #2 “lower extremity” [MeSH] |
| #3 “upper extremity” [MeSH] |
| #4 (#1 OR #2 OR #3) |
| #5 “musculoskeletal manipulations” [MeSH] |
| #6 “manipulation” |
| #7 “manipulation, Chiropractic” [MeSH] |
| #8 “Chiropractic” [MeSH] |
| #9 (#5 OR #6 OR #7 OR #8) |
| #10 (#4 AND #9) |

**Figure 2: Electronic Search Strategy – PubMed**

## Inclusion Criteria

*Types of Studies*
RCTs with parallel or cross-over study design will be included.

*Types of participants*
All study populations with musculoskeletal and non-musculoskeletal conditions or no condition will be considered.

*Types of Interventions*
RCTs that involve chiropractic high-velocity low-amplitude (HVLA) manual interventions will be included. Where treatment includes chiropractic manipulation of, either spinal or extremity (or both) joints, with/without adjunctive therapy (e.g. mobilization, soft tissue therapy, massage, traction, electro-therapies, ultrasound, exercise advice, ergonomic advice, hot/cold therapy, back education).

*Types of Comparators*
RCTs involving chiropractic HVLA interventions verses placebo, sham treatment or conventional/standard/usual care treatment or no treatment will be included.

*Types of care providers*
RCTs involving chiropractors utilizing HVLA interventions will be included.

*Types of terms*
RCTs will be included if the word "chiropractic" appears in the project title, or the project was undertaken by chiropractors or the project was conducted under the auspices of a chiropractic school, or at least one of the authors of the study was a chiropractor.

**Exclusion Criteria**
Non-randomised trial designs (quasi-experimental, observational studies), pilot or feasibility studies, and studies with n-of-1 will be excluded from the review. Studies evaluating diagnostic tests, prevention, prognosis, cost-effectiveness, and validation of questionnaires will also be excluded. Trials not reported as full papers (abstracts), editorials, commentaries, letters, case reports or series, audits, guidelines, historical articles will not be considered for the review. Studies involving instrument-assisted techniques will also not be considered.

**Construction of a customised CONSORT tool**
The methods outlined in this protocol have been modelled upon several published studies assessing the quality of reporting of RCTs from the biomedical literature. (5-7,9-14,26-29,33-35) These studies chose to utilize the CONSORT checklist, as it is considered to have both face and content validity, and is regarded as a suitable measure of methodological quality. (36)

The CONSORT 2010 statement with 25 items was modified by excluding items 21, 22 and 24. Items 21 (generalizability [external validity] of the trial findings) and 22 (interpretation of results) were excluded, as they are difficult to evaluate objectively. (26, 34) Item 24 (access to trial protocol), was also excluded as it is not a requirement to publish protocols prior to publication of trial results.

Several items were also customised by subdivision for clarity, practicality, and so they could be evaluated individually. These are detailed as follows:

- Item 11ai: “whether or not participants were blinded”
- Item 11aii: “whether those assessing the outcomes were blinded to group assignment”.

The question of blinding of care-providers has been excluded for pragmatic reasons inherent in specialised physical therapies. (32, 37) A classic example of this challenge arises when trying to blind surgeons in trials of surgical intervention. (5)

- Item 16i: “number of participants (denominator) in each group included in each analysis; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)”
- Item16ii: “whether analysis was by intention-to-treat”. Item 16, the ITT analysis will be “considered to be adequately reported if method was described, regardless of the actual definition of ITT used”. (26 pg 2)
- Item 17ai: “description for each primary outcome with a summary of results for each group and the estimated effect size and its precision (e.g. 95% confidence interval)”
- Item 17aii: “description for each secondary outcome if applicable”.

All of the included items and their subdivisions are presented in Table 1. In addition, nine items from CONSORT for Non-Pharmacologic Treatment Interventions were deemed appropriate for reviewing chiropractic RCTs and form part of the 39-point customised checklist for scoring the OQR. For clarity they are presented separately in Table 2.

## Assessing the Overall Quality of Reporting (OQR)

The rating methodology for each item will be discussed amongst all authors. Data that is extracted from trials that meet inclusion criteria will be rated independently by at least 2 authors, using the 39-point checklist. Authors will be blinded to each other's results. Results will be collated, and any discrepancies will be resolved via consensus.

Scoring will be performed according to the CONSORT 2010 guidelines and the relevant extension documents. (15,16,21) Items will be defined as 'yes' if they are clearly and adequately reported, or 'no' if they are unclear or not reported at all. Items that are not applicable to a specific study will be defined as 'not applicable' ('N/A'). Each 'yes' answer will received a score of '1' and each 'no' answer will receive a scored as '0', and each 'N/A' answer will be coded with a '9'. Each trial will receive an overall quality rating score (OQRS) that will range between 0–39 points.

## Assessing Key Methodological Items (KMIS)

The additional assessment of KMIS for each trial will be performed separately. The three KMIS that are most commonly used in the biomedical literature from the CONSORT statement are: allocation concealment (Item 9), blinding (Item 11), and use of intention-to-treat analysis (ITT) (Item 16). (6,9,28) In our review, blinding of participants will be scored separately to the blinding of assessors, as such there will be four KMIS: allocation concealment, blinding of participants, blinding of assessors, and use of ITT (refer to Table 3).

## Factors Associated with increased OQR

Predictors that have previously been identified in the medical literature as influencing the reporting quality of RCTs, (6, 9, 28, 38) will be used for our study, such as: industry funding, positive findings, sample size, year of publication and journal type.

**Table 1:** *Items from the customized Overall Quality of Reporting Score (OQRS) checklist extracted from the CONSORT 2010 statement*

| Item | Criterion | CONSORT Description | Total | % |
|---|---|---|---|---|
| 1a | Title | Identification as a randomized trial in the title | | |
| 1b | Abstract | Structured summary of trial design, methods, results, and conclusions | | |
| 2a | Background | Scientific background and explanation of rationale | | |
| 2b | | Specific objectives or hypotheses | | |
| 3a | Trial Design | Description of trial design (such as parallel, factorial | | |
| 4a | Participants | Eligibility criteria for participants | | |
| 4b | | settings and locations where the data were collected | | |
| 5 | Interventions | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | | |
| 6a | Outcomes | Completely defined pre-specified primary and secondary outcome measures, | | |
| 7a | Sample size | How sample size was determined | | |
| 8a | Sequence generation | Method used to generate the random allocation sequence | | |
| 9 | Allocation concealment | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | | |
| 10 | Implementation | Was implementation discussed Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions assigned participants | | |
| 11ai | Blinding | Whether or not participants, were blinded to group assignment | | |
| 11aii | | Whether those assessing the outcomes were blinded to group assignment | | |
| 12a | Statistical methods | Statistical methods used to compare groups for outcome(s) | | |
| 13a | Participant flow | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome | | |
| 13b | | For each group, losses and exclusions after randomization, together with reasons | | |
| 14a | Recruitment | Dates defining the periods of recruitment and follow-up | | |
| 15 | Baseline data | A table showing baseline demographic | | |
| 16i | Numbers Analyzed | Number of participants (denominator) in each group included in each analysis; state the results in absolute numbers when feasible (e.g., 10/20, not 50%) | | |
| 16ii | | “Intention-to-treat” analysis | | |
| 17ai | Outcomes and estimation | Primary outcome a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval) | | |
| 17aii | | Secondary outcome a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval) | | |
| 17b | | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | | |
| 18 | Ancillary Analyses | Results of other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified | | |
| 19 | Adverse events | All important adverse events or side effects in each intervention group | | |
| 20 | Limitations | Trial limitations, | | |

| | | |
|---|---|---|
| 23 | Registration | Registration number |
| 25 | Funding | Sources of funding and other support |

Legend: Total: Total number of trials reporting item; %: Percentage of trials reporting item;

**Table 2:** *Items from the customized Overall Quality of Reporting Score (OQRS) checklist extracted the CONSORT for Non-Pharmacological Treatments statement*

| Item | Criterion | CONSORT Description | Total | % |
|---|---|---|---|---|
| 1ext | Abstract | Does abstract include-description of the experimental treatment, comparator, care providers, centers, and blinding status | | |
| 3ext | Methods | When applicable, eligibility criteria for centers and those performing the interventions (at least one) | | |
| 4aext | Interventions | Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants | | |
| 4bext | | Details of how the interventions were standardized (if training was administered) | | |
| 4cext | | Details of how adherence of care providers with the protocol was assessed or enhanced | | |
| 8ext | Randomization | When applicable, how care providers were allocated to each trial group | | |
| 13ext | Flow Diagram | The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center | | |
| New Item | | Details of the experimental treatment and comparator as they were implemented | | |
| 15ext | Baseline data | Description of care providers (case volume, qualification, expertise, etc.) and centers | | |

Legend: Total: Total number of trials reporting item; %: Percentage of trials reporting item; ext: extension criteria from CONSORT for Non-Pharmacological Treatmen

**Table 3:** *4 Key Methodological Items (KMIS) extracted from customized CONSORT checklist*

| Item No. | Criterion | CONSORT Description | Total | % |
|---|---|---|---|---|
| 9 | Allocation concealment | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | | |
| 11ai | Blinding | Whether or not participants, were blinded to group assignment | | |
| 11aii | Blinding | Whether those assessing the outcomes were blinded to group assignment | | |
| 16ii | Numbers Analyzed | "Intention-to-treat" analysis | | |

Legend: Total: the total number of RCTs that reported this item; %: Percentage of trials reporting item

## Definition of Trial Characteristics

Trials will be considered to be 'industry-funded' if they are at least partially funded by industry. This includes chiropractic research organizations, chiropractic governing bodies or other industry organizations. Item 25 of the tool has been included and defined in this way to make the distinction between the sources of funding that come from funding bodies that may have vested interests in the outcomes of the research and those that do not. Chiropractic departments within private chiropractic colleges that fund research will also be classified as being 'industry-funded'. Chiropractic and non-chiropractic departments within government educational institutions will be classified as 'non-industry-funded.' Trials that do not have any funding will be classified as 'non-industry-funded'.

Positive outcomes will be defined as those producing a statistically significant comparative result reported as a binary "YES" or "NO" outcome. Equivocal results will be coded as "NO". Trials that have more than one hundred participants will be considered as having a 'large' sample size. Trials were considered as published in chiropractic journals, if the journal was dedicated predominantly to the advancement of chiropractic research, education and health care.

## Statistical Analysis

Descriptive statistics will be presented to characterize the overall quality of reporting in chiropractic RCTs as well as the inclusion of key methodological items. The percentage of trials that scored 'yes' to each CONSORT item and each item from the CONSORT for Non-Pharmacologic Treatment Interventions will be tabulated for the OQRS to provide a global assessment of the reporting quality. The percentage of trials that scored 'yes' to KMIS will be tabulated separately and presented also.

A regression analyses will be used to explore whether an associations exists between the outcome measure (i.e. OQRS) and all 5 predictor variables (i.e. industry funding, positive findings, sample size, year of publication and journal type). First we will conduct a univariate regression analysis, which will test all five predictor variables individually. The predictors that produce results that have a $p \leq 0.1$, in the univariate regression analysis, will then be included in the multivariate model.(10, 34) Nonsignificant covariates ($p > 0.05$) in the multivariate analysis will be deleted using a stepwise backward elimination process. In the final multivariate regression model, variables that have $p < 0.05$ will be considered statistically significant. Variation Inflation

Factors (VIFs) will be checked to test for collinearity between predictors. If VIFS are less than ten, then it will be considered that no collinearity exists between variables. All assumptions for normality and linearity will be checked using the Mahalanobis' and Cook's Distance statistics. Outliers will be checked using Cook's Distance statistics. All analyses will be performed using SPSS © 22.0.0.0 (IBM Corporation 2013).

## Ethics, Funding and Dissemination

This project was approved by the Research Ethics and Integrity Office of Murdoch University, Perth, Western Australia (Ethics #2014/119). No funding was obtained for this project. The findings from this study will be disseminated through peer-reviewed journals, national and international conferences.

## Discussion

We have designed a customised 39-item tool, by integrating items from both the CONSORT 2010 (16) and the CONSORT for Non-Pharmacologic Treatment Interventions (21) statements. Previous studies in medicine have also used the CONSORT statements to create a checklist for reviewing the quality of reporting medical RCTs. The initiative to modify CONSORT is not without precedent and has resulted in checklists of varying numbers of items, for example: 11 items (11); 15 items (9, 10, 28, 34); 18 items (26); 19 items (7); 22 items (13); 24 items (6); 25 items (29); and 32 items (5) The benefit of brevity is something that may need to be considered. As a checklist geared towards chiropractic, several of the CONSORT items were viewed as being in need for greater refinement and clarification and so subdividing them was inevitable. Our checklist contains substantially more items than most and it remains unclear whether this will be advantageous or detrimental to a profession that is still evolving its research culture. Nevertheless, the authors believe that as a checklist it offers greater clarity for the construction of chiropractic research protocols than what is presently available.

Assessing KMIS was deemed necessary as they are often under reported even in published trials with high overall reporting scores. (36) Furthermore, the lack of adequate reporting of KMIS is often associated with distortions in estimates of treatment effects. (6) By emphasising KMIS the authors hope to raise awareness and address major weaknesses that have been identified in existing literature.

One of the limitations of this study methodology is that the proposed assessment does not offer any insight into the external validity of the RCTs that are captured. This area is challenging to report upon objectively, (26) as there have not been any scales developed that have been validated to accomplish this task. (34)

As with any scale, another limitation, is that the assessment of quality is dependent on the information available in the published articles. Furthermore, while innovations in modifying and combining two CONSORT checklists are not novel, they do not automatically validate the new tool.

Although the CONSORT for Non-Pharmacologic Treatment Interventions was published in 2008 (21) the authors decided to include trials from 2005, as this was the year that the International Committee of Medical Journal Editors published guidelines that required trials to be registered prior to participant enrolment as a precondition for publishing. (39) Furthermore, there have been several revisions and iterations of the

CONSORT documents since the introduction in 1996. (4) While the original CONSORT items still exist in all the 2001 (40) and 2010 (16) versions of the CONSORT statements there may be some items in which reporting quality is dependent upon the year of publication.

Inclusion and exclusion criteria were challenging to settle upon. Chiropractic therapy involves a wide range of interventions ranging from passive to high velocity manipulations; utilises various methods ranging from manual manipulation to the use of instruments, mechanical devices, props and other stimuli. It also involves various tissues such as vertebral, peripheral, cranial and myofascial. It also frequently involves adjunctive procedures or multiple sites of contact. Thus it can be difficult to encompass all that lies within the scope of practice of chiropractic without becoming over generalised. The authors decided to include RCTs that might broadly be publicly acknowledged as “typical” of chiropractic- i.e. manual manipulation of the spine and extremities with or without adjunctive therapy. It remains unclear whether the checklist developed by the authors would just as effectively be applied under all conditions experienced within chiropractic research. Moreover, by excluding studies that lay claim to being “chiropractic” but did not conform to these criteria, a substantial volume of quality RCT’s may have been omitted that may skew our findings.

## CONCLUSION

Findings from this study will assist in providing recommendations to chiropractic researchers, which may lead to further improving the quality of reporting of chiropractic RCTs. This study may also provide the predictors for better overall quality of reporting.

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