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METHODOLOGICAL ASPECTS OF RESEARCH INTEGRITY AND CULTURE

Investigating the trustworthiness of randomized controlled trials in osteopathic research: a systematic review with meta-analysis

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Abstract

Objectives: To systematically investigate trustworthiness (methodological rigor, transparency, good governance, research integrity, and absence of misconduct) in randomized controlled trials (RCTs) of osteopathic manual therapy.

Methods: This prospectively registered review (PROSPERO-ID: CRD42023457697) searched MEDLINE, EMBASE, CINAHL, AMED, PEDro, ostmed.dr, and Chiroindex for RCTs evaluating osteopathic treatments (January 2021−June 2024). Risk of bias (RoB) was assessed using Cochrane tool 2, while trustworthiness was assessed with the Cochrane Pregnancy and Childbirth Screening Tool and the REAPPRAISED checklist. Journal trustworthiness, misleading representations in abstracts (''spin''), and results plausibility (via meta-analysis) were also assessed. Findings were synthesized descriptively.

Results: Sixty-one RCTs were included (median sample size 45, interquartile range (IQR) 30−76), largely studying healthy volunteers (29%). Most had high RoB (74%), and only 7% acknowledged potential conflicts from authors' professional ties. No journals appeared on cautionary lists, although 23% of articles were published within 2 months of submission. Only 27% of contactable authors engaged with reviewers. Seven abstracts (12%) were free of spin. Methodological concerns included poor missing data handling (31%), selective analyses

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(38%), unacknowledged multiple testing (36%), and outcome switching (12%). Meta-analysis found two outliers and five further with very large effects, while 19% provided inadequate data for pooling.

Limitations include incomplete reports and lack of validated trustworthiness assessment tools.

Conclusion: Adherence to best practices in osteopathic RCTs needs improvement to enhance evidence-based decision-making, reduce research waste, and enhance reproducibility. Further research should explore whether these findings apply to other small, under-resourced fields.

Keywords: Physical therapy modalities; Trustworthiness; Clinical trials; Methodology; Reproducibility; Research integrity

Plain Language Summary

Clinical trials are studies that test if medical treatments work. Doctors and others use these studies to decide how to care for patients or which treatments should be paid for. For clinical trials to be helpful, they need to follow rules to show they can be trusted. For example, researchers can build trust by sharing their plans before they start, reporting all their results honestly and answering questions about their work. In this project, we looked at 61 clinical trials from a 3.5-year period that tested a hands-on treatment called ‘‘osteopathic manual therapy.’’ We checked how well these trials followed the rules for trustworthy research. We found that many trials had problems. For example, important research steps were skipped (such as properly registering the study on appropriate online platforms before starting, following the steps described in the registration documents, and correctly examining the collected data). Often, results were also made to look better than they really are, or it was not clearly explained what happened during the study. Only a few researchers answered questions when we asked them. This shows that some osteopathic trials need to do better so people can trust the results. We also suggest ways researchers can improve trustworthiness in the future.

1. Introduction

The value of randomized controlled trials (RCTs) for research, clinical decision-making, and healthcare policy depends not only on methodological quality but also on research integrity, transparency, and adherence to governance standards, collectively known as the responsible conduct of research [1,2].

Trustworthy research is rigorous, robust, and transparent at all stages [3]. Trustworthiness encompasses good governance, research integrity, and the absence of misconduct [4], which includes fabrication, falsification, [5] and plagiarism [6]. The qualities of trustworthiness are foundational for public trust in science and also serve as indicators of scientific reproducibility, which requires that research processes are sufficiently transparent for independent researchers to follow the methodology, understand the evidence, and verify the findings [7]. Deviations from rigorous research practice, due to knowledge gaps, personal biases, or personal gain, have been documented across various biomedical fields [8]. These issues range from protocol deviations [9−12], questionable analyses [13], data falsification [14−18], plagiarism [6,18], and spin reporting [19−23]. This contributes to research waste and limited reproducibility, undermines public trust, and weakens evidence-based decision-making [1,8,24,25]. Frameworks for a more systematic consideration of trustworthiness [4,26−29], including the UK’s Concordat to Support Research Integrity [30] and the Singapore Statement [31], highlight the values of respect, rigor, honesty, transparency, and accountability.

Failure to demonstrate compliance with these integrity domains undermines trustworthiness of research [25,32,33]. For example, O’Connell et al investigated a subset of trials assessing psychological interventions for pain, the results of which deviated from the remaining literature [14]. Using the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool (CPC-TST), designed to identify potentially untrustworthy trials by considering aspects such as research governance, study feasibility, and results plausibility [28], revealed the need for caution when incorporating these trials into clinical practice or policy. Importantly, trustworthiness issues were not identifiable with common risk-of-bias (RoB) assessment tools. Excluding untrustworthy trials from meta-analyses also reduced the overall estimated effect of the intervention [34]. This example underscores the value of comprehensive trustworthiness reviews across domains of rigor, transparency, and governance. However, focusing solely on preselected samples risks overlooking trustworthiness issues in trials with less striking clinical outcomes.

Systematic reviews assessing trustworthiness across all published articles in a single field are rare, despite the availability of various tools and frameworks [35]. Such reviews could clarify integrity issues and support needs within specific research areas, potentially yielding transferable insights for similar fields. This gap is particularly evident in Allied Health research, such as manual therapies, which faces resource limitations and methodological challenges

What is new?

Key findings

- This systematic review identified multiple areas where researchers in the field of osteopathic manual therapy could improve in demonstrating adherence to the standards of methodological rigor, governance, transparency, and accountability to improve trustworthiness and reproducibility of studies.

What this adds to what was known?

- This is the first systematic review investigating the trustworthiness of randomized controlled trials in a complete field of research, thus offering new insights into current integrity issues in osteopathic manual therapy and into the feasibility of such comprehensive trustworthiness assessments.

What is the implication and what should change now?

- Findings from this review may inform future research integrity initiatives, for example providing training to researchers regarding accessible improvements. In turn, enhancing research trustworthiness may facilitate the integration of osteopathy into evidence-based healthcare and improve patient outcomes.

[36]. One illustrative allied health profession is osteopathic manual therapy, a complex intervention primarily targeting the musculoskeletal system while also considering its relationships with psychosocial aspects of disease and overall health. Practitioners use hands-on techniques, such as manipulation, massage, and stretching, to diagnose and treat various conditions [37]. While osteopathy is a globally growing profession with increasing formal recognition [38], its research base remains small and underfunded, which may pose challenges to the trustworthiness of its research. These resource constraints and methodological challenges may similarly affect other Allied Health fields [39–43]. To facilitate the integration of osteopathy into evidence-based healthcare and promote reproducibility, trustworthy research is essential. This systematic review evaluates the trustworthiness of RCTs of osteopathic manual therapy to inform future research integrity initiatives.

2. Methods

2.1. Protocol and registration

The review was prospectively registered (PROSPERO ID: CRD42023457697), and the protocol was approved by the University College of Osteopathy Research Ethics Committee on 26 July 2023. Reporting is in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA, Supplementary 0) [44].

2.2. Eligibility criteria

We included RCTs of osteopathic interventions in any human population. Eligible studies were published in any language in scientific journals with an editorial process between January 2021 and June 2024. This timeframe was chosen for three following reasons: to increase the likelihood of successfully contacting authors, to provide an up-to-date picture of the field, and to focus on trials conducted in the current research integrity climate where preregistration and reporting standards are more widely established. Nonrandomized studies, gray literature, and secondary analyses of previously published data were excluded.

2.3. Search and study selection

We searched MEDLINE, EMBASE, and AMED through Ovid, and CINAHL, PEDro, ostmed.dr, and chiroindex.org directly. Reference lists of included studies and of recent systematic reviews [45–47] were also screened.

The search strategy was built around the keywords (osteopathy OR osteopathic techniques) AND RCTs (Supplementary 1) and developed in line with relevant guidance [48]. Study selection was performed using Covidence (covidence.org). Duplicates were removed, and two reviewers independently performed title, abstract, and full-text screening. Disagreements were resolved by a third independent reviewer.

2.4. Data extraction

Data extraction domains were bibliographic data, trial design, items for RoB assessment [49], trustworthiness, and spin assessments (Supplementary 2); Participant numbers and baseline and follow-up data for primary outcomes (where declared) were also extracted. Where a primary outcome was not identifiable via author report or specific power analyses, the first-listed outcome measure was extracted.

2.4.1. Trustworthiness assessment

To evaluate studies' compliance with current research integrity standards, the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool (CPC-TST) [28] and the REAPPRAISED checklist [50] were adapted and used. An overview of key items and their operationalization is provided in Table 1 and details in the data extraction form in Supplementary 2. For readability, results are presented per assessed domain, irrespectively of whether items were derived from the CPC-TST or REAPPRAISED.

We did not assess two REAPPRAISED statistics items, as a formal reanalysis of all studies was not feasible with the

Table 1. Key domains of the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool (CPC-TST) and the REAPPRAISED checklist, and their operationalization in this review

Key domains of CPC-TST and REAPPRAISED checklist	Key items and operationalization
Research governance	Verification of prospective registration via trial registries.
	Requesting trial protocols, ethical approval letters, and individual participant data from studies' corresponding authors.
	Communicating with study authors using a structured communication protocol (asking for responses within 2 wks, sending one reminder if needed, allowing for another 2 wks to respond). Documentation of all correspondence.
	Checking journal websites and Retraction Watch Database (retractiondatabase.org) for retractions and expressions of concern.
	Review of funding sources reporting.
	Assessing for evidence of approval by a specific, recognized ethics committee.
	Extracting interest disclosures. Examining disclosures and authors' professional profiles and affiliations for potential conflicts of interest.
Authorship	Extraction of contributorship statements.
Plagiarism	Searching for evidence of copied work using Turnitin. Examining further any similarity scores of $\geq$15% relating to external documents.
Protocol compliance	Where a registered prospective protocol was available, comparison of protocols and final publications for registration dates, target recruitment numbers, power calculations, descriptions of study arms, primary outcome measures, primary assessment/analysis endpoints, and statistical analysis plans.
Feasibility of research conduct	Assessment of study characteristics for implausibility, such as rapid recruitment, implausible session-to-provider ratios and low attrition in complex trials. Requesting explanations from authors if studies reported minimal losses to follow-up or if other questions arose.
	Checking if the numbers randomized to each group suggested adequate randomization methods.
Analysis methods	Assessing if appropriate statistical analysis methods were used.
	Identifying issues with data handling, where possible.
	Examining for outcome switching (where preregistered protocols were available).
	Searching for signs of biased statistical testing (such as ''p-hacking'', unacknowledged multiple testing, and poor methodology regarding missing data management).
Results plausibility	Checking if reported data aligned with logical ranges and participant inclusion criteria.
	Review of each study's results for biological and clinical plausibility.
	Assessment for implausible baseline similarities, unexpected outliers (of individual outcomes or patients, where such data were available), and biologically logical variances over time.
	Comparing effect estimates to other studies using meta-analysis.
Errors	For example, reviewing the consistency of participant numbers at different points of each publication and the accuracy of percentages vs. absolute numbers.

available resources. These items were (1) the compatibility of statistical test results with reported data, and (2) the internal consistency and plausibility of statistical testing results.

2.4.2. *Journal trustworthiness*

To evaluate journals' trustworthiness, Beall's list of potentially predatory journals and the Norwegian Register for Scientific Journals were consulted [51,52]. Inclusion in the Web of Science Master Journal List was also assessed [53].

Submission-to-acceptance times were calculated as potential indicator of journal integrity and peer-review quality [54]. Durations under 2 months were highlighted as unusually fast—a threshold adjusted from the stricter original protocol, based on biomedical journal data [55,56]; indicating it effectively identifies outliers (calculations in Supplementary 3).

2.4.3. *Assessment of spin in article abstracts*

Spin was defined as reporting that could mislead readers by distorting results [57], for example, by claiming treatment effectiveness in the title, emphasizing statistically significant secondary outcomes when primary outcomes are nonsignificant, or inappropriately extrapolating findings to other populations or settings. Spin in publication titles and abstracts was assessed based on criteria from prior studies [58,59].

2.4.4. Risk of bias assessment

To contextualize trustworthiness assessments and meta-analyses with a commonly performed RoB assessment, each trial's RoB was assessed in relation to the extracted outcome, using the Cochrane RoB tool 2 (RoB-2) [49].

2.5. Data analysis

2.5.1. Descriptive analysis

Descriptive analysis summarized noncompliance with trustworthiness and spin items across studies in absolute numbers and percentages. A study-level summary score was not calculated due to large variance in applicable items, influenced, for example, by result significance or preregistration status.

2.5.2. Synthesis of primary outcomes at first follow-up

A meta-analysis of primary outcomes at first follow-up was conducted in RevMan 5.3 to identify outliers and compare results with external studies. Standardized mean change scores with random effects models were used, with analyses grouped by outcome and comparator type. Heterogeneity was assessed using I^2 statistics, outliers identified via forest plots, and publication bias was evaluated with funnel plots. Detailed methods are provided in Supplementary 4.

2.5.3. Exploratory subgroup and correlation analyses

Associations between study characteristics and trustworthiness were planned to be explored using correlation tests but were deemed unfeasible due to the retrieved data's nature and quality and an absence of agreed ways to produce trustworthiness summary scores and cut-off points [60]. Sensitivity analyses according to RoB rating were performed, including only trials with "some concerns" or "low RoB."

3. Results

3.1. Study selection

We included 61 studies (Fig 1, Supplementary 5). Of these, three articles refer to one RCT [61−63], although the reporting is ambiguous and presents different study questions and data. Two articles by Miranda [64,65] reported different outcome measures from the same trial. These articles were analyzed separately. This review's data are freely available at: https://osf.io/rwdp3/.

3.2. Description of the included RCTs

Between January 2021 and June 2024, 61 RCTs of osteopathic manipulative therapy were published, as described in Table 2.

3.3. Publishing process

Articles were published in 32 journals, with the most common being the *Journal of Osteopathic Medicine* (n = 15, 25%), *Journal of Bodywork & Movement Therapies* (n = 5, 8%), *Healthcare* (n = 5, 8%), *International Journal of Osteopathic Medicine* (n = 4, 7%), and *Nature Scientific Reports* (n = 3, 5%).

Scimago rankings (October 2023) classified 34% journals as Q1 (21% of articles), 38% as Q2 (57%), 13% as Q3 (13%), and 16% as Q4 (8%). Six journals (10%) were not listed in the Web of Science but were not flagged as predatory; *Healthcare* (Multidisciplinary Digital Publishing Institute) was "under discussion" at the Norwegian Register for quality concerns.

Submission-to-acceptance times ranged from 17 to 782 days (median: 152; IQR: 64−320), with 14 RCTs accepted in under 2 months.

3.4. Trustworthiness assessment

3.4.1. Research governance

Prospective trial registrations were identified for 24 RCTs (39%) but not for 37 (61%).

Approvals by ethics review boards were reported for all but three trials (5%). On request, 7 (11%) provided an approval letter from an institutional board.

There were no retraction notices or expressions of concern on the Retraction Watch Database.

3.4.2. Authorship

Thirty-four publications (56%) included a detailed contributorship statement, 14 (23%) offered limited or generic statements, and 13 (21%) provided none. Notably, one author was credited with contributions from study conceptualization through manuscript writing one article [63] but was absent from two related publications based on the same study [61,62].

3.4.3. Conflicts of interest

Conflicts of interest (COI) statements were present in all but six reports (10%), with four author groups reporting potential conflicts (7%) and 51 (84%) declaring no conflicts were present. The independent assessment indicated potential vested interests in 43 studies (71%), relationships were deemed unclear in 12 (20%), and COIs were considered not present in six cases (10%). COIs were suspected largely due to professional affiliations of authors and income from teaching or providing osteopathic care, but also in self-funded studies.

3.4.4. Funding

Twenty-four studies were reported as having received no funding (39%). Funding sources or status were not reported in 14 instances (23%). Where reported, funding came from public grants (11, 18% of all trials), educational institutions (9, 15%), professional associations (6, 10%), and private individuals (1, 2%). No industry funding was reported.

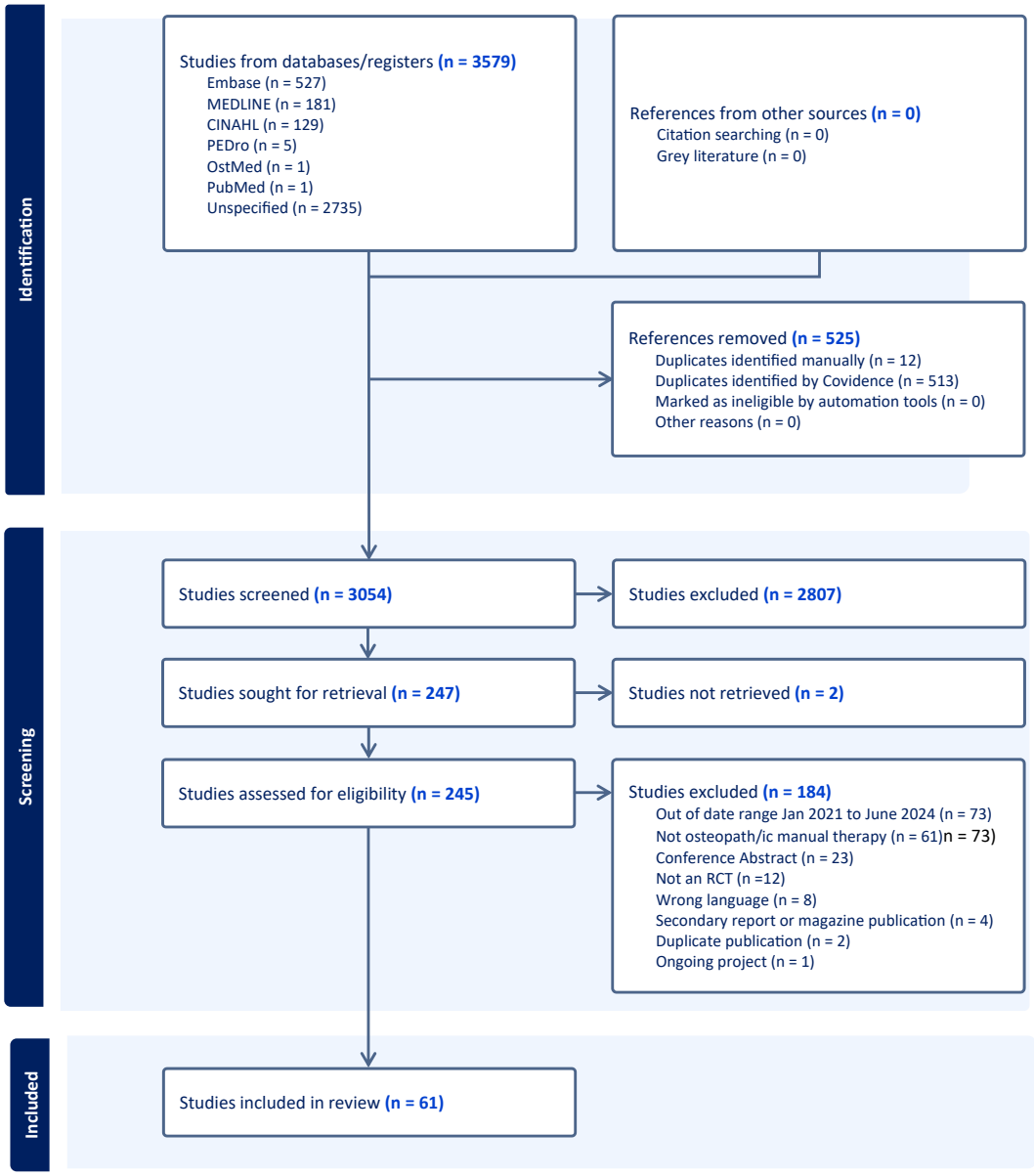

Figure 1. Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) flow diagram of the study selection process.

3.4.5. *Plagiarism*

No significant plagiarism was identified. Eleven publications had >15% similarity to nonself-documents, mostly explainable: one involved standardized text, one matched a lead author's thesis, and five overlapped with unrelated student papers. Here, plagiarism was disproven in two cases and unverifiable in three due to inaccessibility. In two further cases, individual sentences were copied from inaccessible documents.

3.4.6. *Adequacy of publication titles*

Eight publication titles claimed treatment effectiveness (13%), as in: "pain scores improved in patients with back pain…". Nineteen titles (31%) focused on the treatment and disease without mentioning a comparison or randomization or no question about treatment effects.

3.4.7. *Spin reporting in abstracts*

Seven author groups presented publication abstracts without spin (11%). In abstracts' results sections, authors focused on reporting statistically significant within group comparisons (n = 27, 44%) or did not report a point estimate of their result (n = 31, 51%). In the conclusions, 11 authors claimed efficacy with no consideration of nonsignificant results for the primary outcome (41% of applicable cases). Twenty-three (38%) focused their conclusions on within-group assessments (Detailed spin assessments in Supplementary 7).

Table 2. Characteristics of the included studies

Characteristic	Total $n = 61$
Study location[a]	
United States	16 (26%)
Italy	8 (13%)
Brazil	6 (10%)
Germany	6 (10%)
France	5 (8%)
Poland	5 (8%)
Spain	5 (8%)
Australia	3 (5%)
Turkey	3 (5%)
Egypt	2 (3%)
Switzerland	2 (3%)
India	1 (2%)
Portugal	1 (2%)
United Kingdom	1 (2%)
Multinational RCTs (in the above locations)	2 (3%)
Trial design	
Parallel design	51 (84%)
Crossover design	10 (16%)
Alternative designs	2 (3%) factorial (0 adaptive or other alternative designs)
Pilot studies	7 (12%)
Feasibility studies	5 (8%)
2 arms/study conditions	44 (72%)
3 arms	10 (16%)
4 arms	4 (12%)
Participant characteristics	
Total sample size at randomization	Mean 61, range 14–400/median 45, IQR 30–76
Clinical population	Healthy participants or athletes (16, 26%) Back or neck pain (15, 25%) Pediatric (7, 11%) Neurological or psychological problems (3 each, 5%) Temporomandibular, respiratory, cardiovascular, or peripheral joint symptoms (2 each, 3%) Dermatological, ear-nose-throat, gastrointestinal, gynecological, psychiatric, urological, headache, chronic widespread pain, and any musculoskeletal pain (1 each, 2%)
Treatment and comparator characteristics	
Treatment period (in days)	Mean 14, range 1–84/median 21, IQR 1–35 (not reported in 1 case)
Single treatment session	24 (39%) (NR in 1 case)
Comparators or control interventions	(''Placebo''/''sham'') control intervention (31, 51%), another active intervention (21, 34%), no treatment (12, 20%), and usual care (5, 8%)
Follow-up characteristics	
Length of follow-up period after end of treatment (in days)	Mean 41, range 0–364/median 0, IQR 0–30 (NR in 1 case, variable duration in 1 case)
Immediate follow-up only	37 (61%) (NR in 1 case, variable duration in 1 case)
Primary outcomes	
Clearly defined primary or coprimary outcome measure(s)	28 trials (47%)
Primary outcome domain (where primary outcome(s) defined) ($n = 28$)	Pain intensity (12, 43%) Disability (8, 29%) Physiological measure (6, 21%) Physical function (5, 18%) Symptom severity (other than pain intensity) (3, 11%) Study feasibility (2, 7%) Cognition, health-related quality of life, anatomical measure, and composite score of different domains (disability questionnaire + physical function) (1 each, 4%)

(*Continued*)

Table 2. Continued

Characteristic	Total $n = 61$
Method of collecting primary outcome ($n = 28$)	Patient-reported outcome measures (PROM) (17, 61%) Physical function test, biochemical analysis (3 each, 11%) Electrocardiogram (ECG)/pulse oximetry, psychometric test, electromyography (EMG), videopolysomnography, anatomy measurement, ultrasound, and trial process monitoring (1 each, 4%)

[a] *Two trials were conducted in multiple countries, which is why the total number of study locations (n = 64) exceeds the number of included studies (n = 61).*

3.4.8. Protocol comprehensiveness and compliance

Where prospective registration documents were available ($n = 24$, 39%), the consistency of registration items with published articles varied widely. While descriptions of study arms, general trial methods, and dates were usually similar, target recruitment numbers and primary outcome measures frequently differed. Power calculations were only described in detail in one trial registration (2% of entire sample) and statistical analysis plans in 2 (3%) (Table 3).

3.4.9. Feasibility and plausibility of methods and results

Table 4 shows that instances of implausible methods, sample characteristics, and results were rare. However, doubts about the plausibility of conducting the study as described arose in seven cases (12%), for example, when a single interventionist apparently provided 300 treatment sessions over the course of 5 weeks and without study funding. Doubts about the plausibility of losing (close to) zero study participants arose in 12 trials (35%), having taken into consideration the nature of study populations and study timelines.

3.4.10. Methods, analyses, and data

While the rating of methodological adequacy was often hindered by insufficient reporting of data and/or methods, there were frequent concerns about methods for handling missing data ($n = 19$, 31%), the choice of biased or selective tests promoting fragile results (''p-hacking'', $n = 23$, 38%), and unacknowledged multiple testing ($n = 22$, 36%). Data errors were rarely identified, but assessment was limited by lack of access to individual patient data.

3.4.11. Author accountability and data sharing

Emails were sent to 55 of the 61 corresponding authors (90%), with six emails rejected and no alternative email addresses obtainable. Fifteen authors (27% of 55) communicated with the team. Eight of these (15%) provided study protocols and seven (13%) ethics approvals.

In publications, twenty author teams stated data would be made available (33%), eight of whom required ''reasonable requests'' or other conditions for data access. Upon request, datasets were made available for six studies (11%). Of 37 RCTs without prospective registration, four authors (11%) provided reasons. All correspondence with authors is provided as Supplementary 8.

3.5. Risk of bias

Overall RoB was high in 45 trials (74%), some concerns existed for 12 trials (20%), and four trials (7%) had low risk of systematic deviations from intervention effects. Figure 2 shows ratings per bias domain (Study-level ratings in Supplementary 6).

3.6. Meta-analysis of study results

Detailed meta-analysis statistics and figures are provided as Supplementary 4 and the two largest analyses in Figures 3 and 4. Data pooling was possible in 44 studies and not for 17, because reported data could not be converted into a meta-analyzable format ($n = 5$), were insufficient ($n = 2$), or unintelligible ($n = 1$); and ten studies used outcomes that were not comparable to any other studies. Meta-analyses were performed across two dimensions: by outcome domains (pain intensity or sensitivity (Fig 3), disability (Fig 4), physical function, physiological measures, and other subjective symptom severity) and by comparator types (treatments compared to simple (static) touch control interventions; compared to touch-based control intervention maneuvers; compared to other active interventions; and compared to no treatment).

Heterogeneity between studies was considerable ($I^2 = 75\%-100\%$) for studies with pain-related outcomes and disability measures and for analyses grouped by comparator (except for no-treatment comparators; $I^2 = 0\%$). Heterogeneity was low or moderate for physical function outcomes, physiology, and other symptom severity.

Sensitivity analyses of studies with low RoB or ''some concerns'' (Supplementary 4) revealed no noteworthy differences to main analyses.

The confidence intervals (CIs) of most individual studies' effect estimates overlapped with the 95% CI of the summary effect. Exceptions are as follows: Rodriguez-Pastor [66] with a standard mean difference (SMD) of −2.34 (−3.2 to −1.48 95% CI) for pain relief (rated as ''some concerns'' for RoB) and Nikakis [67] (SMD −3.04, −4.01 to −2.08 95% CI) for improvements in a disability measure (high risk). Large effect sizes (>1.0) were also reported by Brück [68], Cerritelli [69], Fernandez-Lopez [70], and Lizis [71] for between-group reductions in pain intensity ratings (Fig 3), and by

Table 3. Protocol compliance

Item assessed for consistency between prospective registration document and publication (assessed in 24 RCTs with prospectively registered information)	Consistent (*n*, % of those with preregistered protocol, and % of total sample)	Protocol or registration only includes rudimentary information on methods, preventing detailed analysis, but yes for what is available (*n*, %, and % of total sample)	Inconsistent (*n*, %, and % of total sample)	No details regarding the respective item in the registration documents (*n*, %)
Details such as dates and study methods	8 (33%; 13%)	7 (29%, 11%)	9 (38%, 15%)	0
Target recruitment numbers	9 (38%, 15%)	3 (13%, 5%)	8 (33%, 13%)	4 (17%)
Power calculations	1 (4%, 2%)	2 (8%, 3%)	5 (21%, 8%)	16 (67%)
Description of study arms	17 (71%, 28%)	5 (21%, 8%)	2 (8%, 3%)	0
Primary outcome measures	15 (63%, 25%)	1 (4%, 2%)	7 (29%, 11%)	2 (8%)
Primary assessment/ analysis endpoints	14 (58%, 23%)	3 (13%, 5%)	5 (21%, 8%)	2 (8%)
Statistical analyses	2 (8%, 3%)	1 (4%, 2%)	2 (8%, 3%)	19 (80%)

Where prospectively registered protocols were available ($n = 24$), items were compared between final study reports and protocol documents.

Amatuzzi [72] for a physiological outcome (Supplementary 4) (all rated as ''high RoB'', except Lizis [71], for which some concerns existed; See Supplementary 6).

Funnel plots were biased toward positive results for the disability subgroup and for trials that compared treatments against no treatment but not for other analyses (Supplementary 4).

3.7. Deviations from systematic review protocol

Protocol deviations in this systematic review include a search period that extended beyond the planned timeframe, discrepancies in categorization between the protocol and manuscript (eg, research governance vs protocol compliance), the omission of two REAPPRAISED statistics items due to resource constraints, and the exclusion of subgroup and correlation analyses, which were deemed unfeasible due to the nature and quality of the data and the lack of agreed-upon trustworthiness summary scores. Upon reviewer request, sensitivity analyses by RoB rating were added for meta-analyses.

4. Discussion

This review of 61 osteopathic RCTs published over a 3.5-year period highlighted several areas where authors could better demonstrate adherence to standards of methodological rigor, transparency, and accountability. Positively, most studies used credible methods, reported plausible data and results, and no plagiarism was detected. Conversely, concerns arose about transparency and compliance with best scientific practices. Only 57% of trials were prospectively registered, and inconsistencies between registered protocols and published articles were frequent. Power calculations and statistical analysis plans were missing in most protocols, and handling of missing data was either inadequately reported or omitted. Around one-third of trials exhibited selective testing or did not account for multiplicity. Only 12% of author teams reported results in abstracts without ''spin,'' often focusing on within-group changes or not reporting key outcome data. Authors' responsiveness to requests for essential study documents or clarifications was limited. For one author group, there was initial ambiguity about whether data reported across three separate reports originated from the same clinical trial; the author later confirmed that this was the case. Compared to Cochrane meta-analyses in subacute and chronic low back pain, the summary effects reported here were considerably larger [73,74]; RoB ratings mirrored other osteopathy-related reviews [45] and tended to be less favorable than in comparable Cochrane reviews [73,74]. Collectively, these issues raise concerns about the trustworthiness and reproducibility of many of the findings from the reviewed trials.

Adherence to best research practices is often limited across various fields, not just osteopathic manual therapy. For example, compliance with established reporting standards remains limited in manual therapies [75], exercise [76], prehabilitation [77], and social and psychological intervention trials [78]. Reporting completeness varies across journals [79], highlighting the need for editorial enforcement of reporting checklists [80]. ''Spin'' has been attested in several fields too [20–23]. However, editorial advice can fail to curb spin or improve statistical reporting [81], highlighting potential gaps in the peer review process and the need for improved interventions earlier in the research cycle.

Adherence to other quality standards, such as trial preregistration and protocol compliance, is also lacking in many fields. Lack of preregistration undermines

Table 4. Results of trustworthiness assessment according to CPC-TST and REAPPRAISED checklist

Assessment item	Yes	No	Unclear/questionable	Not applicable
Feasibility and plausibility of methods and results				
Study methods plausible, at the location specified	55 (90%)	4 (7%)	2 (3%)	0
Study sample free from characteristics that could be implausible	59 (97%)	2 (3%)	0	0
Plausible explanation in cases with (close to) zero losses to follow-up	22 (65% of 34 applicable cases)	12 (35% of 34 cases)	1 (2%, no information on attrition)	26 (43%): not applicable as no loss to follow-up
Study free from results that could be implausible	58 (95%)	3 (5%)	0	0
Numbers randomized to each group suggest that adequate randomization methods were used	57 (93%)	2 (3%)	2 (3%, insufficient data to rate)	0
Recruitment of participants plausible within the stated time frame for the research	49% (80%)	0	12 (20%, no recruitment timeframe reported)	0
Number of participant withdrawals compatible with the disease, age, and timeline	53 (87%)	6 (10%)	2 (3%, no information on withdrawals)	0
Study plausibly completed as described	54 (89%)	7 (12%)	0	0
Data methodology and rigor				
Correct analyses undertaken and reported	41 (67%)	No, or doubts about appropriateness: 17 (28%)	3 (5%) (insufficient information to rate)	0
No evidence of poor methodology regarding missing data[a]	13 (21%)	19 (31%)	29 (48%, missing data handling not reported)	0
No evidence of poor methodology regarding inappropriate data handling[a]	14 (23%)	2 (3%)	45 (74%, data handling not reported)	0
No evidence of poor methodology, including ''p-hacking'' (biased or selective analyses that promote fragile results)[a]	35 (57%)	23 (38%)	3 (5%, unclear due to limited reporting)	0
No evidence of poor methodology, including other unacknowledged multiple statistical testing[a]	36 (59%)	22 (36%)	3 (5%, unclear due to limited reporting)	0

(*Continued*)

Table 4. Continued

Assessment item	Yes	No	Unclear/questionable	Not applicable
Analysis plan compliance				
No 'outcome switching', i.e., analysis and discussion focusing on measures other than those specified in registered analysis plans[a]	23 (38%)	7 (12%)	0	31 (51%): no analysis plan available, irrespective of whether prospectively or retrospectively registered
Data plausibility and errors				
Features or outcomes of subgroups compatible with those of the whole cohort[a]	38 (63%)	0	0	23 (38%): no subgroups reported
Reported summary data compatible with the reported range	52 (85%)	0	0	9 (15%): no ranges reported
Summary outcome data not identical across study groups[a]	60 (98%)	0	1 (2%): no summary data reported	0
No discrepancies between data reported in figures, tables and text[a]	47 (77%)	11 (18%)	0	3 (5%): no data, tables, or figures reported
No implausible data[a]	57 (93%)	2 (3%)	4 (7%): no data reported	0
Baseline data not excessively similar or different between randomized groups[a]	54 (89%)	4 (7%)	3 (5%): no baseline data reported	0
None of the outcome data unexpected outliers[a]	57 (93%)	4 (7%)	0	Note that individual patient data were not reported/ available, so that individual outliers could not be assessed
No data outside the expected range for sex, age, or disease[a]	59 (97%)	1 (2%)	1 (2%): relevant data not reported	0
No discrepancies between the values for percentage and absolute change[a]	17 (28%)	0	44 (72%): no percentage or absolute change reported	0
No discrepancies between reported data and participant inclusion criteria[a]	60 (98%)	0	1 (2%): relevant data not reported	0
Variances in biological variables not surprisingly consistent over time[a]	59 (97%)	0	2 (3%): relevant data not reported	0
Interval between study completion and manuscript submission plausible	50 (81%)	0	12 (19%): study dates not reported	0
Correct and consistent numbers of participants throughout the publication	56 (92%)	3 (5%)	2 (3%): no participant flow reported	0

(*Continued*)

Table 4. Continued

Assessment item	Yes	No	Unclear/questionable	Not applicable
Calculations of proportions and percentages correct	41 (67%)	0	20 (33%): no proportions/ percentages reported	0
Results internally consistent	57 (93%)	3 (5%)	1 (2%): insufficient data reported	0
No other data errors[a]	58 (95%)	3 (5%)	0	0

[a] Note that formulation of these items has been modified from the original checklist items to enable presentation of results with the same valency (ie, ''Yes'' indicating positive, and ''No'' negative implications for trustworthiness).

trustworthiness as retrospective or unregistered trials exhibit higher RoB [82] and report more favorable outcomes [83,84]. The low proportion (40%) of prospectively registered osteopathic trials in this review aligns with the 42% in a review of over 7000 trials in various healthcare domains [9]. Said review also showed that preregistration is less common in smaller trials. Even correctly registered trials can exhibit selective outcome reporting [10–12]. While editorial policies, such as self-declared adherence to International Committee of Medical Journal Editors (ICMJE) recommendations [85], have limited impact [9], legal frameworks have proven more effective [84]. In studies like this review, it is reported that authors fail to choose appropriate statistical tests, raising concerns about the validity of their findings [86–88]. This lack of rigor is compounded by transparency issues, such as unclear ethical approvals and inadequate data-sharing practices [89,90]. Authors often fail to comply with their own data-sharing statements [91]; Mirroring our findings, corresponding authors frequently ignore, distract from, or indefinitely delay data sharing, citing barriers such as lack of personal responsibility, patient consent, or access to data [91]. In other fields, even the veracity of entire datasets has been questioned [14–18]. No such concerns arose here.

This review faced several limitations, including the reliance on often incomplete RCT reports and the focus on RCTs from a recent but brief time frame. Additionally, there are no validated frameworks for assessing trustworthiness [26,35,92], which complicated the evaluation process. The breadth of potentially relevant concerns [60] and the operational limitations of the CPC-TST and the REAPPRAISED checklist required the development of customized reviewer guidance, extensive training, and ongoing supervision to ensure consistency.

Another challenge was the absence of validated methods to summarize trustworthiness into summary scores [60]. Resultingly, we could not formally assess the impact of limited trustworthiness on reported treatment effects. However, by grouping comparable studies for meta-analyses, we were able to identify several studies with inexplicably large effects, which itself served as a useful trustworthiness check.

This review also focused on a small field. While similar problems are present across biomedical trials, the generalizability of our findings is unclear. Nevertheless, this review provides a comprehensive, up-to-date analysis of a complete research field, offering insights that could inform support initiatives for osteopathic manual therapy researchers and possibly other small professions.

Our approach to systematically assessing trustworthiness also produced valuable lessons. For example, we found that objective measures (such as the presence of preregistration) were preferable to subjective assessments (eg, study plausibility) or assessments that depend on rarely reported information (eg, individual-level patient data). These insights contribute to the developing field of

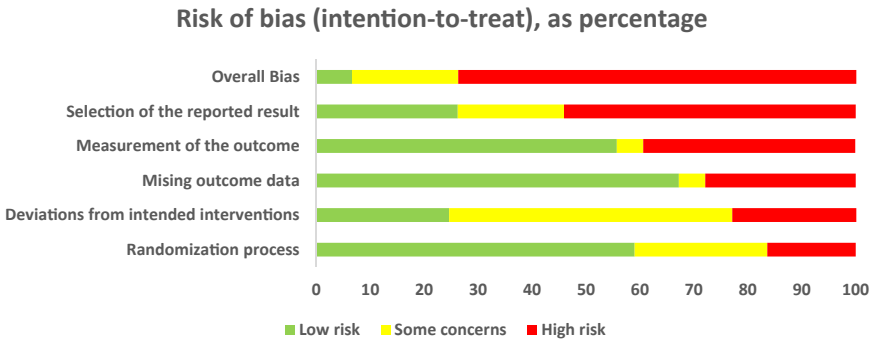

Figure 2. RoB summary graph for the included studies (n = 61), as rated with the Cochrane RoB tool 2 (Rob-2).

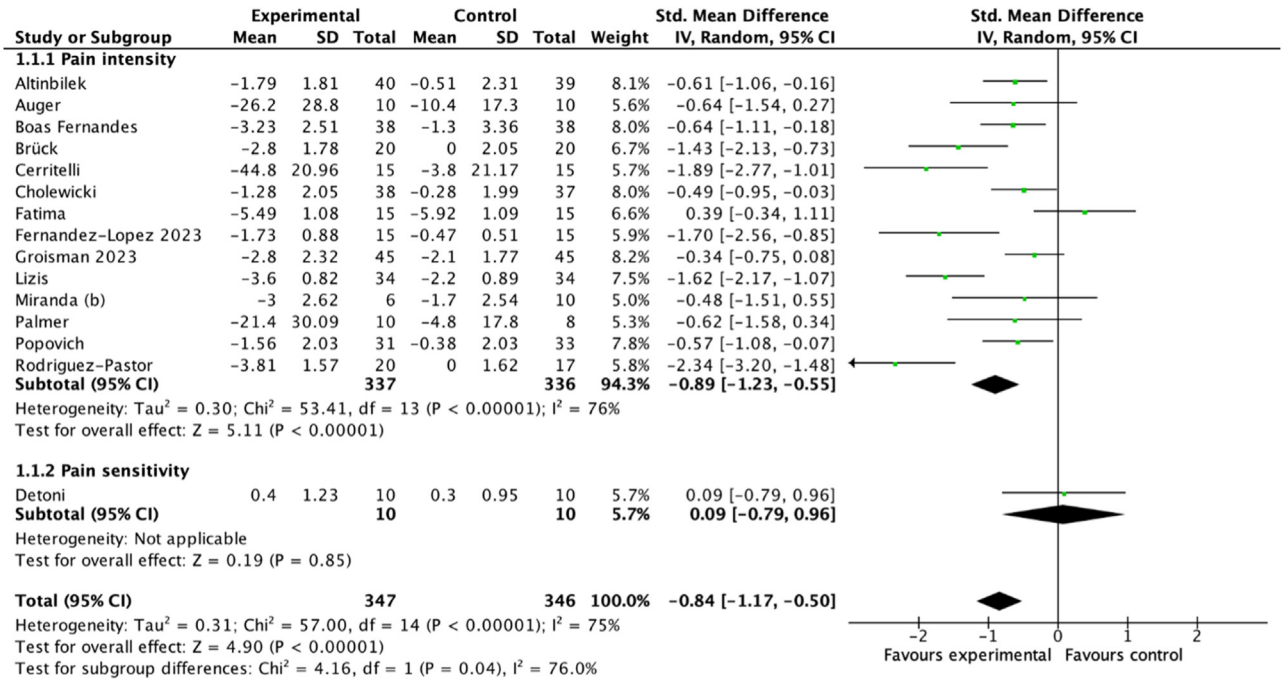

Figure 3. Forest plot of meta-analyzed studies assessing pain intensity or pain sensitivity.

trustworthiness investigations [60]. Consensus-based frameworks for trustworthiness assessments are being developed [16] and may incorporate these lessons. However, such frameworks will require validation [27,35,92] and should consider how the results of trustworthiness checks can be formally incorporated into evidence syntheses.

The issues highlighted in this review reflect a broader concern with the quality and trustworthiness of medical research in general and underscore the need to understand the underlying causes. Commonly cited reasons are limited research skills, insufficient resources to obtain expert support, and incentive structures that prioritize publication quantity and positive results [8,93]. These pressures are exacerbated in smaller fields like osteopathy, where researchers may lack access to the necessary expertize or infrastructure to conduct high-quality studies.

4.1. Enhancing trustworthiness in under-resourced research fields

The use of scarce resources should be monitored carefully [94]. Ethics boards and funders are often called upon to prevent low-quality research from being conducted [25,94] and journals from publishing it [32,95]. However, this review shows that in small research fields, these calls may be limited: Many studies were self-funded, and ethical review was often performed by small teaching institutions, whose review boards may lack technical knowledge or sufficient independence [96–98]. Most journals in this review did not uphold quality standards through editorial and peer review processes, suggesting limited effectiveness as gatekeepers of high-quality research. Scarce resources also imply that researcher training may be limited, and

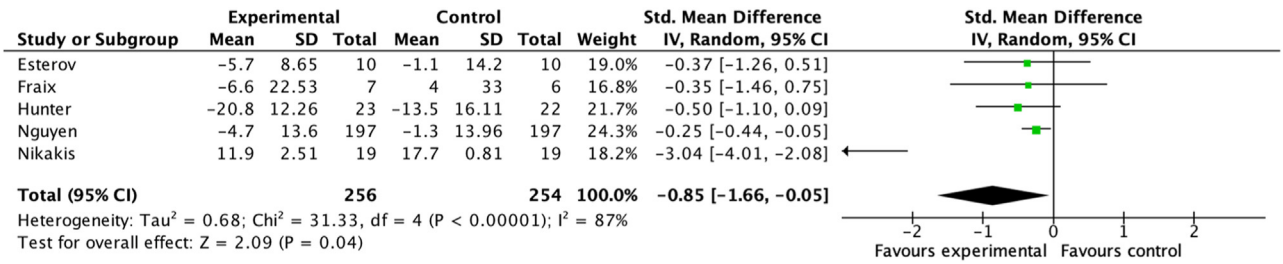

Figure 4. Forest plot of meta-analyzed studies assessing disability.

Table 5. Simple steps for researchers to enhance the trustworthiness of their work

Step	Description/Elaboration
Seek mentorship and build expertize	Gain experience through mentorship, formal collaborations, and educational opportunities before leading RCTs. Engaging in systematic reviews, qualitative studies, or working on others' projects can help develop essential research skills.
Acknowledge mistakes and be prepared to learn from them	Transparency about mistakes and openness to critical feedback should be fundamental values for researchers, enabling them to improve future work.
Ensure feasibility before scaling up	RCTs should begin with feasibility or pilot studies to refine methods, address challenges, and build a case for funding. High-quality evidence synthesis can also inform study design.
Engage stakeholders early	Engage with key stakeholders—clinicians, patients, and policymakers — during the planning phase. Involving diverse perspectives can highlight important questions or practical barriers that isolated research teams may overlook — apart from promoting methodologically quality, feasibility, relevance, and translation of research.
Fully adopt good governance practices	Adhering to ethical guidelines and governance standards aims to ensure that trials are high-quality, ethical and impactful. Rather than hindering research, proper governance - like independent ethical review, comprehensive pre-registration, compliance with data protection and storage regulations, and open data sharing - builds public trust, enhances the reliability and reproducibility of findings, and ensures that resources are used efficiently. Researchers must allow for sufficient time to fully comply with governance processes.
Balance innovation and feasibility	Aim for methodologically rigorous yet feasible study designs within resource constraints. Avoid over complication and ensure transparency in reporting limitations.
Ensure methodological rigor and reproducibility	Only start an RCT if the necessary expertize and support are in place. Adhere to current methodological and reporting standards, provide clear documentation, and facilitate reproducibility through open data sharing.
Be transparent and accountable	Transparency is required at every stage, from preregistration to the final report. When mistakes are acknowledged, data shared, and limitations acknowledged upfront, being responsive to queries and accountable for mistakes will feel natural.
Embrace Open Science practices	Learn about Open Science practices and its inherent values [99], incorporating as many Open Science principles as possible within a given setting.
Engage in high-quality peer review and constructive critique	Submit to respected journals and collaborate with peer reviewers to uphold scientific standards. Preprints and open platforms provide valuable alternatives for early feedback. Offering constructive criticism strengthens the research community.

The focus of this list is on straightforward steps that researchers can take immediately and without large-scale funding or institutional support. For each step, multiple, freely accessible resources are available and continue to be developed. Notably, however, a shared commitment to upholding fundamental standards of quality, transparency, and research integrity is at the core of producing trustworthy science in smaller and under-resourced research communities.

collaborations with clinical trials units or established research institutions — which could improve trial quality — are rare.

While some argue that conducting no trial is preferable to conducting a low-quality trial [1,25], we propose that researchers in under-resourced fields can still achieve better quality and more trustworthy research by focusing on accessible improvements. These steps are outlined in Table 5. To support researcher's methodological training, many free resources tailored to RCTs are available (examples in Box 1). Support initiatives also exist within the osteopathic profession (https://ncor.org.uk/starshot/).

From the findings of this systematic review, we suggest that producing trustworthy science needs to be based on a shared commitment to upholding the core values and standards of quality, transparency, and research integrity [29,100]. We recognize that researchers in small fields may lack experience in conducting RCTs and must therefore be willing and open about seeking support and collaboration to achieve higher quality research outputs. It is essential to submit research projects and reports to rigorous governance processes and peer reviews. In developing a supportive community, more experienced researchers also need to be willing to aid when requested and offer honest, constructive critiques where required.

While this approach places the onus on the researcher, it does not absolve institutions, funders, ethics boards, and editors from doing their share to support small research fields. Comprehensive frameworks to promote trustworthy research through both the involvement of governance structures and the promotion of researcher integrity have recently been developed [29].

Box 1 Resources for clinical trial researchers. English-language examples only.

Trial Forge (based in Aberdeen, Scotland): Collection of resources: https://www.trialforge.org/

Irish Health Research Board Trials Methodology Research Network (HRB-TMRN): Collection of resources: https://www.hrb-tmrn.ie/

Patient-Centered Outcomes Research Institute (PCORI) (US-based): Collection of resources: https://www.pcori.org/

UK Trial Managers' Network: Collection of resources: https://www.tmn.ac.uk/

UK National Institute for Health and Care Research (NIHR): Clinical Trials Toolkit: Toolkit: https://www.ct-toolkit.ac.uk/

US National Institute for Health (NIH): Research Methods Resources: Collection of resources: https://researchmethodsresources.nih.gov/

World Health Organisation (WHO): Guidance for best practices for clinical trials: https://www.who.int/publications/i/item/9789240097711.

Ethics statement and consent to participate

The project was approved by the University College of Osteopathy Research Ethics Committee on 26 July 2023. Consent for participation was deemed not applicable.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used ChatGPT-4o in the writing process in order to improve the readability and language of the manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

CRediT authorship contribution statement

Amandine Sénéquier: Writing − review & editing, Writing − original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Jerry Draper-Rodi:** Writing − review & editing, Writing − original draft, Supervision, Methodology, Funding acquisition, Conceptualization. **Gerard Alvarez Bustins:** Writing − review & editing, Investigation, Data curation. **Felicity Braithwaite:** Writing − review & editing, Investigation, Data curation, Conceptualization. **Jessica Brown:** Writing − review & editing, Investigation, Data curation. **Daniel Corcoran:** Writing − review & editing, Investigation, Data curation. **Laura Forrest:** Writing − review & editing, Investigation, Data curation. **Elianne Godsi:** Writing − review & editing, Investigation, Data curation. **Andrew MacMillan:** Writing − review & editing, Investigation, Data curation. **Mathieu Menard:** Writing − review & editing, Investigation, Data curation. **Sonia Roura Carvajal:** Writing − review & editing, Investigation, Data curation. **Concetta Scocca:** Writing − review & editing, Investigation, Data curation. **Loïc Treffel:** Writing − review & editing, Investigation, Data curation. **Paul Vaucher:** Writing − review & editing, Investigation, Data curation. **Agathe Wagner:** Writing − review & editing, Investigation, Data curation. **Nadia Soliman:** Writing − review & editing, Writing − original draft, Supervision, Methodology, Conceptualization. **Hilary Abbey:** Writing − review & editing, Writing − original draft, Visualization, Validation, Supervision, Project administration, Investigation, Formal analysis, Data curation. **David Hohenschurz-Schmidt:** Writing − review & editing, Writing − original draft, Visualization, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

Amandine Sénéquier reports financial support from the UK National Council for Osteopathic Research (NCOR). She reports employment in private practice as an osteopath and with Queen Mary University of London, which also provided funding grants. She had a consulting relationship with Altern Health Ltd.

Jerry Draper-Rodi received financial support from the Osteopathic Foundation. He reports employment with NCOR and involvement with Osteopathy Europe, where he received funding grants, non-financial support, and travel reimbursements. He also had non-financial support and travel reimbursements from the University of Technology Sydney's Faculty of Health - Australian Research Center in Complementary and Integrative Medicine. Additionally, he reports speaking and lecture fees from Kookie Learning and Metropolia University of Applied Sciences, consulting fees from the College of Health Sciences Fribourg, and employment in private osteopathic practice.

Gerard Alvarez received financial support from NCOR. He reports employment with the Faculty of Health Science Blanquerna, Ramon Llull University, Barcelona, Spain, and board membership and employment in private osteopathic practice.

Felicity Braithwaite reports financial support from NCOR. She received funding grants from The Hospital Research Foundation - Arthritis, the Medical Research Future Fund, and the National Health and Medical Research Council. She also reports speaking fees and travel reimbursements from the San Diego Pain Summit, Australian Physiotherapy Association, Australian Podiatry Association,

Medicine Education Science and Health (MESH), and Noigroup, as well as speaking fees from the Australian Pain Society (where she served as a board member) and the European Pain Federation. She received travel reimbursements from the International Association for the Study of Pain.

Jessica Brown reports financial support from NCOR and employment in private osteopathic practice.

Daniel Corcoran received financial support from NCOR and reports employment with Victoria University.

Laura Forrest reports financial support from NCOR and employment in private osteopathic practice.

Elianne Godsi reports financial support from NCOR. She reports employment in private osteopathic practice and received speaking and lecture fees from The BCNO Group, British College of Osteopathic Medicine.

Andrew MacMillan received financial support from NCOR. He reports being an honorary research fellow at Health Sciences University and working as a practicing osteopath and researcher. He reports employment by NHS England as an advanced practice reviewer, and Circle Integrated Care as an advanced practice osteopath. He also receives income from delivering Continued Professional Development training to healthcare professionals.

Mathieu Menard reports financial support from NCOR. He was employed by the Institut d'Ostéopathie de Rennes - Bretagne, served as an associate researcher at the M2S lab of the University of Rennes 2, and was a member of the International Advisory Board of the International Journal of Osteopathic Medicine (IJOM).

Sonia Roura reports financial support and travel reimbursement from NCOR. She also reports employment in private osteopathic practice.

Concetta Scocca reports financial support from NCOR and employment in private osteopathic practice and by The BCNO Group.

Loïc Treffel reports employment in Institut Toulousain d'Ostéopathie; financial support for Continuing Professional Development in Osteopathy, fees for providing osteopathic clinical services; non-financial support and travel reimbursement from University of Technology Sydney's Faculty of Health - Australian Research Center in Complementary and Integrative Medicine.

Paul Vaucher works as a private independent clinician in osteopathic care, serves as CEO of OsteoPole (a company providing education and research services), is a board member of the Foundation COME Collaboration, and is an associate editor at IJOM. He received funding from the Swiss Osteopathic Science Foundation, the School of Health Sciences Western Switzerland, and received accommodation and travel cost coverage for various talks at osteopathic congresses in Europe.

Agathe Wagner reports financial support from NCOR. She reports employment with the European Center for Higher Education in Osteopathy, employment in private osteopathic practice, and membership on the International Advisory Board of IJOM.

Nadia Soliman reports a relationship with Imperial College London that included employment and research funding grants.

Hilary Abbey reports financial support and employment with NCOR, and a role as Honorary Visiting Professor at Health Sciences University - UCO School of Osteopathy.

David Hohenschurz-Schmidt received consulting fees from Altern Health Ltd. and income from private osteopathic practice. He reports employment with Health Sciences University and Imperial College London, and or self-employed income from Osteopathie Schule Deutschland and Haute école de santé Fribourg, where he received honoraria for teaching and supervision. He served on the executive committee of the Society for Back Pain Research, the Scientific Committee for the 2026 International Association for the Study of Pain (IASP) World Congress, and as an editor at BioMed Central Medical Research Methodology. He also received research funding from The Osteopathic Foundation, the Alan and Sheila Diamond Charitable Trust, the UK National Institute for Health and Care Research (NIHR), the Chelsea and Westminster Hospital Joint Research Council, and personal support through prizes or conference travel awards from International Association for the Study of Pain, BritSpine, and the European Pain Federation. He received personal honoraria for research from the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION).

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Data availability

This review's data are freely available at: https://osf.io/rwdp3/.

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