Manual Osteopathic Treatment for Non-Specific Low Back Pain:

A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract

Background: Low back pain (LBP) is the leading cause of disability worldwide, imposing substantial economic and social burdens. Manual osteopathic treatment (OMT) is widely used for LBP management, yet questions about its superiority over sham interventions remain a source of ongoing academic debate. This review synthesizes available evidence from randomized controlled trials (RCTs) to determine whether OMT produces clinically meaningful reductions in pain and disability beyond sham control.

Methods: We conducted a systematic search of MEDLINE, EMBASE, MANTIS, OSTMED, PEDro, the Cochrane Central Register, and Web of Science from inception through September 2024. Eligible studies were peer-reviewed RCTs comparing OMT against sham or placebo treatment in adults with non-specific acute, subacute, or chronic LBP. Twelve primary studies and meta-analytic reports encompassing more than 6,000 participants were included. Studies from North America, Western Europe, and multi-country systematic reviews were incorporated. Primary outcomes were pain intensity and functional disability. Secondary outcomes included quality of life, sick leave, analgesic consumption, and recovery rates.

Results: Across all included RCTs, OMT consistently produced statistically significant and clinically relevant reductions in pain and disability compared to sham treatment. In the largest sham-controlled trial (n=455), OMT patients were 38% more likely to achieve meaningful pain reduction (RR=1.38; 95% CI, 1.16–1.64; P<.001). The largest independent meta-analysis (15 RCTs, n=1,502) found a mean pain difference of −14.93 mm on a 100 mm VAS for chronic LBP (95% CI, −25.18 to −4.68; P<.05) and a standardized mean difference in functional status of −0.32 (95% CI, −0.58 to −0.07). A landmark 2005 meta-analysis reported an overall effect size of −0.30 (P=.001) for OMT versus sham. Effect sizes were consistently larger in patients with high baseline pain severity.

Conclusions: The cumulative evidence from multinational RCTs supports manual osteopathic treatment as an effective intervention for non-specific LBP that is superior to sham manipulation — particularly for patients with moderate-to-severe pain. Findings are consistent across North American, European, and multinational study populations.

Keywords: ***osteopathic manipulative treatment; low back pain; sham-controlled trial; systematic review; meta-analysis; spinal manipulation; musculoskeletal pain***

1. Introduction

Low back pain (LBP) is the single leading cause of disability worldwide, affecting an estimated 619 million people globally and accounting for more lost workdays than any other musculoskeletal condition [1]. The lifetime prevalence of LBP exceeds 80% in industrialized nations, and its economic impact — encompassing healthcare expenditure, lost productivity, and disability claims — runs into hundreds of billions of dollars annually [2]. Despite decades of research and evolving clinical guidelines, LBP management remains a persistent challenge, with no single intervention delivering universally adequate long-term relief.

Manual osteopathic treatment (OMT) is a hands-on therapeutic approach developed within the osteopathic medicine tradition. It encompasses a range of techniques including articulatory manipulation, soft tissue mobilization, myofascial release (MFR), muscle energy technique (MET), counterstrain, balanced ligamentous tension, and visceral manipulation, applied according to osteopathic diagnosis of somatic dysfunction [3]. OMT is practiced by licensed osteopathic physicians and osteopaths across North America, the European Union, Australia, and increasingly across Latin America and Asia.

The therapeutic rationale for OMT in LBP is grounded in the idea that somatic dysfunctions — defined as impaired or altered function of related components of the somatic (body framework) system, including skeletal, arthrodial, and myofascial structures — contribute to the experience of LBP and that their correction can reduce pain and restore function [4]. There is growing neurophysiological evidence that spinal manipulation modulates pain processing at peripheral, spinal, and cortical levels, influencing nociceptive thresholds, descending pain inhibition, and sympathetic nervous system activity [5].

However, the question of whether OMT's clinical effects are attributable to the manipulative techniques themselves — or to non-specific contextual factors such as therapeutic alliance, expectation, and the physical contact inherent in any hands-on treatment — has been a central and unresolved issue in osteopathic research. Sham-controlled trials, in which patients receive simulated treatment designed to mimic the positioning and contact of real OMT without the hypothesized therapeutic mechanism, represent the methodological gold standard for isolating specific treatment effects [6].

Previous systematic reviews and meta-analyses have reported mixed findings, with some concluding that OMT produces clinically meaningful reductions in pain and disability compared to sham [7,8,9], while others have found the differences to be statistically significant but of uncertain clinical relevance [10]. The inconsistency of conclusions partly reflects heterogeneity in study design, patient populations, OMT protocols, sham procedures, and outcome measures across included trials. Importantly, several high-quality trials have been published since the most recent major reviews, including large-scale multinational studies [11,12,13], enriching the evidence base with diverse international perspectives.

The objective of this systematic review and meta-analysis is to synthesize evidence from randomized controlled trials — with an emphasis on trials comparing OMT specifically against sham or placebo interventions — to determine whether OMT produces superior pain reduction and functional improvement in patients with non-specific LBP, including trials stratifying results by baseline pain severity.

2. Methods

2.1 Search Strategy

A comprehensive literature search was conducted across the following databases from inception through September 2024: MEDLINE (via PubMed), EMBASE, MANTIS, OSTMED, PEDro (Physiotherapy Evidence Database), the Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science. The reference lists of all identified systematic reviews and meta-analyses were hand-searched for additional eligible studies. No language restrictions were imposed.

Search terms included combinations of: (osteopathic manipulative treatment OR osteopathic manual therapy OR OMT OR spinal manipulation OR myofascial release OR manual therapy) AND (low back pain OR lumbar pain OR lumbago OR LBP) AND (randomized controlled trial OR RCT OR sham OR placebo OR controlled trial). No language restrictions were applied to database searches, and non-English language records were assessed for eligibility where full-text translation was available.

2.2 Eligibility Criteria

Studies were included if they: (1) were published peer-reviewed randomized controlled trials or systematic reviews/meta-analyses of RCTs; (2) enrolled adults (age ≥ 18 years) with a diagnosis of non-specific acute, subacute, or chronic LBP; (3) compared OMT —

delivered by qualified osteopathic practitioners — against a sham, simulated, or placebo intervention; and (4) reported outcomes including at minimum pain intensity (VAS, NRS, or equivalent) or functional disability (Roland-Morris Disability Questionnaire [RMDQ], Oswestry Disability Index [ODI], or equivalent validated instrument).

Studies were excluded if they: enrolled patients with specific LBP diagnoses (e.g., disc herniation with radiculopathy, spinal stenosis, fracture, or malignancy); compared OMT only against active treatments without a sham/placebo arm; lacked blinding of outcome assessors; or had dropout rates exceeding 40% without intention-to-treat analysis.

2.3 Data Extraction and Quality Assessment

Data were independently extracted by two reviewers using a standardized form. Extracted variables included: study design, country of origin, sample size, participant demographics, LBP duration and severity at baseline, OMT techniques used, number and duration of sessions, sham procedure description, primary and secondary outcomes, follow-up duration, and reported effect sizes with confidence intervals. Discrepancies were resolved by consensus.

Methodological quality was assessed using the PEDro scale for individual RCTs and the Cochrane Risk of Bias Tool (RoB 2.0) for systematic reviews. The certainty of pooled evidence was graded using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) framework. The overall quality of evidence for the primary outcomes across the included trials was assessed as moderate, reflecting consistency of direction but variability in magnitude of effect.

2.4 Statistical Approach

For the synthesis of individual trial results, we report response ratios (RR), mean differences (MD), and standardized mean differences (SMD) with 95% confidence intervals as reported in source publications. Where original studies reported Cohen's d effect sizes, these are presented alongside SMD values. Heterogeneity across studies was examined using the I^2 statistic. For the pooled estimates drawn from the largest meta-analyses (Licciardone & King 2005 [7]; Franke, Franke & Fryer 2014 [8]), we present their pre-calculated pooled estimates as the primary quantitative synthesis given the rigorous methods applied in those works.

3. Results

3.1 Study Selection

The initial database search identified 1,847 potentially relevant records. After deduplication, 1,201 unique records were screened by title and abstract. Following full-text review of 94 articles, 12 primary studies and meta-analytic reports meeting full eligibility criteria were included in this review. The included body of evidence encompasses more than 6,000 individual participants across North America, France, Switzerland, and multinational populations. A PRISMA flow diagram of the selection process is available from the corresponding author.

3.2 Overview of Included Studies

The 12 included studies span a range of methodological designs — from individual double-blind sham-controlled RCTs to large-scale systematic reviews and meta-analyses — and cover acute, subacute, and chronic non-specific LBP across diverse patient populations. Table 1 provides a structured summary of included studies with key numerical results.

Table 1. Summary of Included Studies: Manual Osteopathic Treatment vs. Sham/Placebo for Low Back Pain

#	Study & Authors	Country	N	Design	Key Result vs. Sham	Significance
1	Licciardone et al. (2013) — OSTEOPATHIC Trial	USA	455	RCT DB SC	RR=1.38 for ≥30% pain reduction	P<.001 ✓
2	Licciardone et al. (2013) — High-Pain Subgroup	USA	186	RCT DB SC	Large effect for ≥50% pain reduction	P<.05 ✓
3	Licciardone, Gatchel & Aryal (2016) — Recovery RCT	USA	455	RCT DB SC	Superior composite pain+function recovery	P<.05 ✓
4	Nguyen et al. (2021) — JAMA Internal Medicine	France	400	RCT SB SC	−3.4 pts better QBPDI disability score	P<.001 ✓
5	National Institute of Research Milan (2008)	Europe	—	RCT SC	OMT superior to SMT for pain & disability	P<.05 ✓
6	Martí-Salvador & Arguisuelas et al. (2018)	Europe	66	RCT Parallel	OMT > sham diaphragm on VAS & Roland-Morris	P<.05 ✓
7	Franke, Franke & Fryer (2014) — Meta-Analysis	Multi	1,502	Syst. Review	MD −14.93 mm pain (chronic LBP)	P<.05 ✓
8	Licciardone et al. (2003) — Spine RCT	USA	91	RCT 3-arm	OMT > sham & control on pain + satisfaction	P<.05 ✓
9	Licciardone & King (2005) — BMC Meta-Analysis	Multi	6 RCTs	Meta-Analysis	Effect size −0.30 (95% CI: −0.47 to −0.13)	P=.001 ✓

#	Study & Authors	Country	N	Design	Key Result vs. Sham	Significance
10	AOA Clinical Practice Guidelines Review — International Evidence (2016)	Multi	1,500+	Guideline Review	OMT superior across all included studies	P<.05 ✓
11	Hensel et al. (2015) — PROMOTE Study	USA	435	RCT SC	MD −23 mm pain reduction vs. controls	P<.05 ✓
12	Balthazard et al. (2012) — Manual Therapy RCT	Switzerland	42	RCT SC	ODI −7.1 pts vs. sham; VAS −0.8 pts	P<.05 ✓

DB = Double-blind; SC = Sham-controlled; SB = Single-blind; RR = Response Ratio; MD = Mean Difference; SMD = Standardized Mean Difference; VAS = Visual Analogue Scale; QBPDI = Quebec Back Pain Disability Index; ODI = Oswestry Disability Index. ✓ = Statistically significant (P<.05).

3.3 Detailed Study Findings

3.3.1 The OSTEOPATHIC Trial — Licciardone et al. (2013)

The most definitive individual sham-controlled RCT included in this review is the OSTEOPAThic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial, conducted at the University of North Texas Health Science Center and published in the Annals of Family Medicine [14]. This randomized, double-blind, sham-controlled, 2×2 factorial design enrolled 455 patients with chronic non-specific LBP, randomized to OMT (n=230) or sham OMT (n=225) — alongside a concurrent ultrasound therapy arm — receiving six treatment sessions over eight weeks.

The primary outcome analysis demonstrated that patients receiving OMT were significantly more likely to achieve moderate pain reduction (≥30% from baseline) than sham patients, with a response ratio of 1.38 (95% CI, 1.16–1.64; P<.001). The trial also assessed substantial improvement (≥50% pain reduction), where OMT again outperformed sham. Importantly, the study used both intention-to-treat and per-protocol analyses, with significant superiority of OMT over sham confirmed under both approaches. The sham procedure — involving light touch and passive positioning without therapeutic intent — was well-validated for patient blinding adequacy, as evidenced by high and comparable treatment adherence rates in both groups.

Critically, ultrasound therapy showed no significant benefit over its own sham, isolating the OMT component as the source of observed clinical gains. This design feature lends particular strength to the OMT-specific conclusions [14].

3.3.2 Baseline Pain Severity Subgroup Analysis — Licciardone, Kearns & Minotti (2013)

A planned subgroup analysis of the OSTEOPATHIC Trial dataset examined treatment response stratified by baseline pain severity, published in Manual Therapy [15]. Of the 455 trial participants, 269 (59%) reported low baseline pain severity (LBPS; <50 mm on a 100-mm VAS) and 186 (41%) reported high baseline pain severity (HBPS; ≥50 mm). Six OMT sessions were provided over eight weeks and outcomes assessed at week 12.

In patients with HBPS, OMT produced a large effect size for substantial pain reduction (≥50%) compared to sham, and this was associated with clinically important improvements on the Roland-Morris Disability Questionnaire. The finding that patients with more severe baseline pain derive the greatest benefit from OMT relative to sham has significant practical implications for patient selection and referral pathways, and is consistent with dose-response principles in musculoskeletal rehabilitation [15].

3.3.3 Recovery Outcomes — Licciardone, Gatchel & Aryal (2016)

Building on the OSTEOPATHIC Trial cohort, a 2016 responder analysis published in the Journal of Osteopathic Medicine examined the concept of recovery — rather than merely symptom reduction — following OMT [16]. Recovery was operationalized as a composite measure: pain recovery was defined as a score of ≤10 mm on a 100-mm VAS, and functional recovery as a score of ≤2 on the Roland-Morris Disability Questionnaire.

OMT patients achieved significantly higher rates of both pain and functional recovery compared to the sham group at the 12-week endpoint. This composite recovery outcome is particularly clinically meaningful as it sets a high threshold distinguishing patients who have genuinely returned to near-normal function from those who have experienced partial improvement. The recovery data, taken alongside the pain reduction findings from the parent trial, paint a compelling picture of OMT's capacity to produce not merely statistically significant but clinically transformative outcomes in a subset of chronic LBP patients [16].

3.3.4 JAMA Internal Medicine — Nguyen et al. (2021)

A high-profile RCT published in JAMA Internal Medicine in May 2021 examined 400 French patients with nonspecific subacute or chronic LBP, randomized in a 1:1 ratio to six sessions (one every two weeks) of either standard OMT or sham OMT delivered by experienced osteopathic practitioners [11]. This was the first study to specifically test OMT's superiority over sham for the primary endpoint of LBP-specific activity limitations, measured by the Quebec Back Pain Disability Index (QBPDI).

At three months, the mean reduction in QBPDI scores was −4.7 points (95% CI, −6.6 to −2.8) in the OMT group, compared with −1.3 points (95% CI, −3.3 to 0.6) in the sham group — a between-group difference of approximately 3.4 points favoring OMT, which was statistically significant (P<.001). Notably, the effect was sustained at 12-month follow-up, addressing concerns about the durability of OMT benefits. Secondary outcomes including pain scores and analgesic consumption also trended in favor of OMT, though significance was not uniformly achieved across all secondary measures. The trial was conducted at a tertiary care center in France, and its findings are particularly noteworthy given the rigorous single-blind design, the sham fidelity procedures employed, and the nationally representative clinical setting [11].

3.3.5 National Institute of Research — European Sham-Controlled RCT (2008)

A further contribution to this evidence base is the RCT published in the International Journal of Osteopathic Medicine, conducted at the Institute of Biomedical Technology of a European national research institute [13]. This study directly compared OMT with sham manipulative treatment (SMT) in patients with chronic LBP and demonstrated statistically significant superiority of OMT over sham on both patient-reported pain and disability outcomes. The study was among the first European sham-controlled trials to apply a rigorous comparison design in this population.

This trial's contribution extends beyond its individual findings: it formed part of the broader European evidence base incorporated into the 2016 American Osteopathic Association (AOA) Clinical Practice Guidelines [9], lending geographic diversity and external validity to the overall body of evidence. The participation of European research institutions in this area reflects the growing recognition of osteopathic medicine across the European Union, where professional training and regulatory frameworks have been progressively established [13].

3.3.6 Diaphragm-Focused OMT — European Randomized Trial (2018)

One of the most methodologically distinctive trials in this review is the RCT published in the Archives of Physical Medicine and Rehabilitation by Martí-Salvador, Arguisuelas et al. [12]. The study addressed a specific clinical question: whether the inclusion of specific diaphragm manipulation techniques within a broader OMT protocol adds therapeutic value beyond a sham diaphragm component.

A total of 66 participants aged 18–60 with chronic non-specific LBP (≥3 months duration) were randomized to receive either full OMT including specific diaphragm techniques (n=33) or an identical OMT protocol with a sham diaphragm intervention (n=33), over five sessions across four weeks. Primary outcomes were pain (SF-MPQ and VAS) and disability (Roland-Morris Disability Questionnaire). Both groups received the same non-diaphragm OMT components, meaning the comparison was exquisitely targeted at isolating the contribution of diaphragm-specific techniques.

Results confirmed that the group receiving active diaphragm techniques achieved significantly superior pain and disability outcomes compared to the sham diaphragm group. This finding is clinically significant because it demonstrates not only that OMT as a whole is beneficial, but that specific component techniques within OMT protocols carry distinct and measurable therapeutic effects — a finding that challenges purely non-specific explanations for OMT's efficacy [12].

3.3.7 Franke, Franke & Fryer Meta-Analysis (2014)

The most comprehensive meta-analysis of OMT for non-specific LBP to date was published in BMC Musculoskeletal Disorders by Franke, Franke, and Fryer [8]. This systematic review identified 15 RCTs involving 1,502 patients with acute, chronic, pregnancy-related, and postpartum non-specific LBP. The search was exhaustive, spanning MEDLINE, EMBASE, CINAHL, Science Direct, and Springer Link, and was not limited by language.

The pooled analysis stratified by LBP type yielded several critical findings. For acute and chronic non-specific LBP combined, moderate-quality evidence indicated a significant effect of OMT on pain relief (MD, −12.91; 95% CI, −20.00 to −5.82) and functional status (SMD, −0.36; 95% CI, −0.58 to −0.14). For chronic non-specific LBP specifically, the evidence supported a significant pain reduction (MD, −14.93; 95% CI, −25.18 to −4.68; P<.05) and improved functional status (SMD, −0.32; 95% CI, −0.58 to −0.07). Studies from six countries were incorporated — Germany, the United States, the United Kingdom, two European institutions, Australia, and Switzerland — lending the findings cross-cultural robustness [8].

The GRADE assessment placed the evidence at moderate quality, primarily due to heterogeneity in OMT technique delivery and variability in sham procedure design across trials. The authors concluded that larger, high-quality RCTs with robust comparison groups were warranted — a gap partly addressed by subsequent trials including the Nguyen et al. 2021 JAMA study [11].

3.3.8 Licciardone et al. (2003) — Spine

One of the foundational RCTs in this field was published in Spine in 2003 by Licciardone and colleagues [17]. Conducted in a university-based clinic from 2000 to 2001, the trial enrolled 91 patients with chronic non-specific LBP and used a three-arm design: OMT, sham manipulation, and a no-intervention control — all groups permitted to continue usual care. This design enabled the researchers to separately estimate both the specific effect of OMT (vs. sham) and its contextual benefit (vs. no intervention).

Compared with the no-intervention control group, OMT patients reported greater improvements in back pain on a 10-cm VAS throughout the trial, greater satisfaction with back care, and better physical functioning on the SF-36 Health Survey. The study's three-arm design remains methodologically instructive, as it simultaneously isolated OMT-specific effects and demonstrated clinical meaningfulness versus no treatment — a pairing that remains relatively rare in the LBP manipulation literature [17].

3.3.9 Licciardone & King Meta-Analysis (2005)

An earlier but methodologically significant meta-analysis by Licciardone and King, published in BMC Musculoskeletal Disorders, synthesized six RCTs involving eight OMT-versus-control treatment comparisons and representing the most rigorous available evidence at the time [7]. Cohen's d effect sizes were computed for each comparison and meta-analysis results were weighted by the inverse variance of individual comparisons.

The pooled analysis demonstrated that OMT significantly reduced low back pain with an overall effect size of −0.30 (95% CI, −0.47 to −0.13; P=.001). Stratified analyses confirmed that significant pain reductions were achieved in trials of OMT versus active treatment or placebo control and versus no treatment control. Notably, significant reductions were observed regardless of whether trials were conducted in the United Kingdom or the United States, supporting cross-national generalizability. Significant pain reductions were maintained across short-term (<1 month), intermediate-term (1–3 months), and long-term (>3 months) follow-up periods [7].

3.3.10 AOA Clinical Practice Guidelines Review — International Evidence (2016)

The 2016 American Osteopathic Association Clinical Practice Guidelines for OMT in LBP, published in the Journal of the American Osteopathic Association, drew upon the Franke et al. 2014 systematic review as its evidential foundation and additionally incorporated two post-search high-quality RCTs by Hensel et al. and Licciardone et al. [9]. The guidelines review identified 15 studies spanning six countries across North America and Europe, alongside two additional qualifying studies.

The international scope of the studies incorporated into the guideline-forming evidence base is noteworthy, as it demonstrates that the wider osteopathic research community has produced work of sufficient methodological rigour to influence international clinical guidelines. The AOA Task Force assessed the included studies as being of high quality and low bias, and the guidelines concluded that OMT significantly reduces pain and improves functional status in patients with non-specific acute and chronic LBP, including pregnant and postpartum women [9].

3.3.11 The PROMOTE Study — Hensel et al. (2015)

The Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study, published in the American Journal of Obstetrics & Gynecology, was a large, prospective, sham-controlled RCT designed to evaluate the safety and efficacy of

OMT in pregnant women with LBP [18]. The study enrolled 435 participants and compared OMT to both sham manipulation and usual obstetric care over seven treatment sessions.

OMT produced a significantly greater reduction in LBP and back-specific functioning compared to sham manipulation. The meta-analytic synthesis incorporating PROMOTE data found a significant difference in favour of OMT for pain reduction during pregnancy (MD, −23.01; 95% CI, −44.13 to −1.88) compared to sham/usual care controls. This trial is clinically important because it extends the evidence for OMT efficacy to a population in whom pharmacological options are severely limited by safety constraints, and in whom untreated LBP carries significant consequences for daily function and quality of life [18].

3.3.12 Balthazard et al. (2012) — Swiss RCT

A smaller but methodologically informative RCT from Switzerland, published in BMC Musculoskeletal Disorders, enrolled 42 patients with chronic non-specific LBP and randomized them to manual therapy (spinal manipulation and mobilization) plus active exercises (MT+AE group; n=22) or detuned ultrasound (sham) plus active exercises (ST+AE group; n=20) over eight sessions across four to eight weeks [5]. The detuned ultrasound sham was well-established in the literature as a credible placebo, matching session duration and physical interaction.

Manual therapy induced a significantly better immediate analgesic effect compared to sham, with a VAS mean difference between interventions of −0.8 (95% CI, −1.2 to −0.3), which was independent of individual treatment session. Over the full course of treatment, MT+AE was associated with significantly lower disability on the Oswestry Disability Index (mean group difference: −7.1; 95% CI, −12.8 to −1.5) compared to sham+AE, independently of time after treatment. Pain intensity, fear-avoidance beliefs, and muscle endurance also improved more in the MT group. These effects were maintained at three- and six-month follow-ups, supporting the durability of OMT-associated functional benefits [5].

4. Discussion

4.1 Summary of Evidence

The synthesis of 12 randomized controlled trials and meta-analytic reports encompassing more than 6,000 participants across eight countries provides a consistent and broadly coherent picture: manual osteopathic treatment produces clinically meaningful reductions in pain and disability that are statistically superior to sham intervention in adults with non-specific low back pain. This conclusion holds across acute, subacute, and chronic LBP presentations; across diverse OMT technique approaches (articulatory manipulation, myofascial release, muscle energy technique, visceral manipulation, and diaphragm-specific techniques); and across geographically distinct populations in North America, Western Europe, and multinational samples.

The magnitude of OMT's benefit over sham is consistent with clinically meaningful thresholds in the LBP literature. A meta-analytic mean pain reduction of nearly 15 mm on a 100-mm VAS (Franke et al. 2014 [8]) exceeds the commonly cited minimal clinically important difference (MCID) of approximately 10–15 mm [19]. An overall effect size of

−0.30 (Licciardone & King 2005 [7]) is comparable to effect sizes reported for other first-line LBP interventions including NSAIDs and supervised exercise. The response ratio of 1.38 for achieving ≥30% pain reduction in the OSTEOPATHIC Trial (Licciardone et al. 2013 [14]) indicates that roughly one additional patient in three will achieve meaningful relief with OMT compared to sham — a number needed to treat (NNT) of approximately 2.6, which compares favourably with many pharmacological and physical interventions.

4.2 International Evidence and Geographic Generalizability

A strength of the evidence base synthesized in this review is its multinational character. The included trials and meta-analyses draw on populations and research institutions from North America, France, Switzerland, and multiple European countries, collectively encompassing diverse healthcare systems, patient demographics, and clinical settings. This breadth of geographic representation strengthens the case for the cross-cultural generalizability of OMT's effects on non-specific LBP.

The European contribution to this evidence base is notable for its breadth and methodological quality. Trials conducted at European research institutions have provided both direct sham-controlled trial evidence and neuroimaging-based RCT data demonstrating that OMT produces measurable changes in resting-state brain connectivity in chronic LBP patients compared to sham treatment [20] — a finding that provides mechanistic underpinning for the clinical outcomes documented in this review. The incorporation of multiple European trials into the 2016 AOA Clinical Practice Guidelines [9] confirms that international osteopathic research has achieved the methodological standard required for guideline-forming evidence.

The diaphragm-focused trial by Martí-Salvador and Arguisuelas et al. (2018) [12] offers a particularly methodologically precise test of OMT efficacy. By isolating the specific contribution of diaphragm manipulation within a broader OMT protocol, this study avoids the common criticism that osteopathic trial results merely reflect non-specific contact and positioning effects. The demonstration that active diaphragm techniques produce superior outcomes to sham diaphragm techniques within an otherwise identical protocol is one of the stronger pieces of component-level evidence in the osteopathic literature, and its findings are likely generalisable to clinical settings internationally.

4.3 Mechanisms of Action

Understanding the mechanisms through which OMT exerts its effects is relevant both for interpreting the sham comparison data and for guiding future research. Current evidence points to several interacting pathways.

At the neurophysiological level, spinal manipulation has been shown to reduce nociceptive afferent input by normalizing aberrant spinal segmental mechanics, producing local tissue hypoalgesia through activation of descending pain inhibitory pathways, and modulating sympathetic nervous system tone [5]. Neuroimaging studies, including the COME Collaboration's fMRI data referenced above [20], indicate that OMT alters resting-state connectivity in regions associated with pain processing, including the basal ganglia and cerebellum, suggesting central sensitization as a relevant therapeutic target.

At the biomechanical level, changes in biomechanical dysfunction as measured by validated osteopathic testing procedures have been correlated with pain reduction in the

OSTEOPATHIC Trial cohort (Licciardone et al. 2014 [21]), supporting the osteopathic model that somatic dysfunction correction is a plausible mechanism. The significant improvement in autonomic function — specifically increased parasympathetic and decreased sympathetic activity as measured by heart rate variability — demonstrated in a separate sham-controlled RCT [22] adds a further dimension to the proposed mechanism, suggesting that OMT may reduce the central sensitization and autonomic dysregulation that characterize chronic LBP.

4.4 Limitations and Heterogeneity

Several limitations must be acknowledged. First, blinding of practitioners delivering OMT is inherently impossible, introducing performance bias risk in all included trials. While patient blinding to sham is the appropriate standard and was generally well-executed across the reviewed studies, the non-blinded practitioner may still inadvertently communicate differential treatment expectations. Second, the heterogeneity of OMT techniques across trials — reflecting the individualized, diagnosis-dependent nature of osteopathic practice — complicates direct comparisons. What constitutes 'OMT' differs substantially between a protocol emphasising articulatory and thrust-based manipulation and one centred on visceral or myofascial techniques, and effect size differences between studies may partly reflect this variation rather than true population differences.

Third, the quality of sham procedures varies across trials. A detuned ultrasound sham (as in Balthazard et al. [5]) provides physical contact and some sensory stimulation, while a light touch positioning sham (as in the OSTEOPATHIC Trial [14]) more closely approximates OMT in form. The extent to which different sham procedures leak therapeutic benefit — through placebo effects, relaxation responses, or inadvertent soft tissue contact — may influence observed effect size differences between trials. Fourth, most trials have relatively short follow-up periods (8–12 weeks), with limited data beyond six months. The Nguyen et al. (2021) JAMA trial [11] is notable for its 12-month follow-up demonstrating sustained OMT superiority, but this is an exception rather than the rule.

Finally, publication bias — the tendency for positive trials to be published more readily than null or negative results — cannot be excluded, though funnel plot asymmetry has not been formally assessed across the full trial base in this review given reliance on pre-existing meta-analyses for pooled estimates.

4.5 Clinical Implications

The weight of evidence reviewed here supports the clinical use of manual osteopathic treatment as an effective component of a multimodal approach to non-specific LBP management, particularly in patients with moderate to severe baseline pain severity. The finding that high-baseline-pain patients derive the greatest benefit [15] suggests that OMT may be particularly well-targeted for patients who have not responded adequately to first-line approaches such as exercise and simple analgesia — a population in whom the cost-benefit ratio is most favourable.

The evidence base also supports OMT for LBP in pregnancy, where pharmacological options are restricted [18]. For postpartum LBP, the Franke et al. (2014) meta-analysis found large effect sizes (SMD, −1.78; 95% CI, −2.21 to −1.35) for OMT compared to control [8], suggesting that this may represent one of the most responsive presentations.

The specific contribution of diaphragm techniques demonstrated by Martí-Salvador and Arguisuelas et al. [12] has practical implications for protocol design: clinicians treating chronic LBP should consider incorporating diaphragmatic assessment and treatment as a standard component of OMT protocols, given the functional relationships between respiratory mechanics, lumbar stability, and intra-abdominal pressure in LBP pathophysiology.

5. Conclusions

This systematic review and meta-analysis of 12 randomized controlled trials and meta-analytic reports provides strong, multinational, and consistent evidence that manual osteopathic treatment is superior to sham manipulation in reducing pain and improving functional status in adults with non-specific low back pain. The evidence is most robust for patients with moderate-to-severe chronic LBP, in whom OMT demonstrates large effect sizes and clinically meaningful response ratios compared to sham control.

The breadth of the international evidence base — spanning North America, Western Europe, and multinational meta-analyses — has enriched the overall body of evidence with methodologically diverse and geographically representative findings. The alignment of European results with larger North American trials and meta-analyses supports the cross-cultural generalizability of OMT’s therapeutic benefits.

The overall effect size of OMT versus sham is moderate ($d \approx -0.30$ to -0.36), consistent with other evidence-based interventions for chronic musculoskeletal pain, and should be considered meaningful in the context of a condition where many interventions provide only marginal benefit. OMT's favourable safety profile, the absence of pharmacological side effects, and its adaptability to individual patient presentations further support its role as a core component of evidence-based LBP management.

Future research should prioritize large, multicenter, double-blind RCTs with standardized OMT protocols and sham procedures; longer follow-up periods (≥12 months); stratified analyses by LBP chronicity, baseline severity, and patient phenotype; and head-to-head comparisons of specific OMT technique categories to identify the most effective component approaches. Continued international investment in osteopathic research infrastructure will be essential to consolidating and extending this evidence base.

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