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# **CRITICAL REVIEW**

# Osteopathic manipulative treatment for chronic nonspecific neck pain: A systematic review and meta-analysis

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<b>KEYWORDS</b> Neck pain; Osteopathic manipula- tive treatment; Spinal manipulation; Systematic review	<ul> <li>Abstract Objectives: Nonspecific neck pain is common, disabling, and costly. The objective of the current review was to assess the effectiveness of osteopathic manipulative treatment (OMT) in the management of chronic nonspecific neck pain regarding pain, functional status, and adverse events.</li> <li>Study selection: A systematic literature search unrestricted by language was performed in March 2014 in several electronic databases and in databases of ongoing trials. A manual search of reference lists and personal communication with experts identified additional studies. Only randomized clinical trials were included, and studies of specific neck pain or single treatment techniques were excluded. Primary outcomes were pain and functional status, and secondary outcome was adverse events.</li> <li>Data extraction: Studies were independently reviewed using a standardized data extraction form. Mean difference (MD) or standard mean difference (SMD) with 95% confidence intervals (CIs) and overall effect size were calculated for primary outcomes. GRADE was used to assess quality of the evidence.</li> <li>Data synthesis: Of 299 identified studies, 18 were evaluated and 15 excluded. The 3 reviewed studies had low risk of bias. Moderate-quality evidence suggested OMT had a significant and clinically relevant effect on pain relief (MD: -13.04, 95% CI:</li> </ul>
	95% confidence intervals (CIs) and overall effect size were calculated for primary outcomes. GRADE was used to assess quality of the evidence. <i>Data synthesis:</i> Of 299 identified studies, 18 were evaluated and 15 excluded. The 3 reviewed studies had low risk of bias. Moderate-quality evidence suggested OMT
	-20.64 to $-5.44$ ) in chronic nonspecific neck pain, and moderate-quality evidence

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suggested a non-significant difference in favour of OMT for functional status (SMD: -0.38, 95% CI: -0.88 to 0.11). No serious adverse events were reported. *Conclusion:* Based on the 3 included studies, the review suggested clinically relevant effects of OMT for reducing pain in patients with chronic nonspecific neck pain. Given the small sample sizes, different comparison groups, and lack of long-term measurements in the few available studies, larger, high-quality randomized controlled trials with robust comparison groups are recommended. © 2015 Elsevier Ltd. All rights reserved.

Implications for practice

- The review suggested clinically relevant effects of OMT for reducing pain in patients with chronic nonspecific neck pain.
- This finding will be useful for osteopaths because it supports the use of OMT for patients with neck pain.
- Readers should be aware that the evidence is of moderate quality, and that larger, highquality randomized controlled trials are required to confirm these findings.

# Introduction

Neck pain is experienced by people of all ages; it is as ubiquitous as headaches, abdominal pain, or back pain, and often follows an episodic course similar to low back pain.<sup>1,2</sup> Common in the general population, neck pain has 12-month prevalence estimates ranging from 30% to 50% in adults and from 21% to 42% in children and adolescents.<sup>2</sup> Although neck pain may be persistent and debilitating, neck pain that limits activity is less common than disabling low back pain.<sup>2</sup> Neck pain of unknown origin is commonly referred to as nonspecific neck pain.<sup>1</sup>

Osteopathy is a health approach that emphasizes the role of the musculoskeletal system in health and promotes optimal function of the tissues of the body.<sup>3</sup> Osteopathic manipulative treatment (OMT) typically involves a range of manual techniques. Treatment is characterized by a holistic approach to the patient, and OMT may be applied to many regions and tissues of the body, sometimes remote from the symptomatic area, at the clinical judgement of the practitioner.<sup>3–5</sup>

Even though patients with neck pain visit osteopaths for treatment, the number of patients consulting osteopaths is unclear. In the United Kingdom, osteopaths were estimated to perform 4.38 million treatments in 1998.<sup>6</sup> Neck symptoms are a common presenting complaint of patients in osteopathic practice in the United Kingdom, second only to low back symptoms, and accounted for 15% of presenting symptoms in a national pilot survey<sup>7</sup> and 37% in a snap-shot survey.<sup>8</sup> Similarly, in Australia neck symptoms accounted for 24.5% of complaints, second to low back symptoms.<sup>9</sup> In the United States, where osteopathic physicians have full medical licence, neck pain has been reported to account for 11% of musculoskeletal presentations, following lumbar spine, head, and thoracic spine symptoms.<sup>10</sup>

To our knowledge, no systematic review exists for the treatment of neck pain with OMT. Although research funding bodies favour technique-specific treatment protocols rather than discipline-specific approaches, reviews of discipline-specific treatment of musculoskeletal pain still have an important role and are found in discipline and nondiscipline-specific journals alike.<sup>11–17</sup> There is a need for systematic reviews of the effectiveness of OMT. The osteopathic profession in many countries is emerging and unregulated and such reviews are important for the justification of services and regulation. An osteopathic treatment approach is arguably different from single manual technique interventions and other manual therapy treatments and it is unknown whether OMT produces benefits to patients with neck pain and, if so, the magnitude of treatment effects. The objective of this review was to assess the effectiveness of OMT in the management of chronic nonspecific neck pain regarding pain, functional status, and adverse events in randomized clinical trials with adult patients compared with control treatments (no treatment, sham, and all other treatments).

# Methods

# Criteria for considering studies for the current review

The research methods and reporting of this study followed PRISMA guidelines.<sup>18</sup>

# Types of studies

Only randomized controlled trials (RCTs) were included in the current review. Potential studies could be published or unpublished (grey literature) in any language.

# Types of participants

We included studies of adults (18 years and older) with chronic nonspecific neck pain, defined as pain that is localized to the cervical region, and with a duration of pain greater than 3 months. We excluded studies of specific neck pain, defined as pain with a specific cause, such as a compression fracture, tumour, metastasis, or infection.

# Types of interventions

Treatment was required to be an OMT intervention performed by an osteopath or osteopathic physician who had a choice of manual techniques, without any technique restrictions or standardized treatment protocols, and used clinical judgement for the treatment selection. Techniques had to be chosen based on the treating practitioner's opinion of what techniques would be most appropriate for the patient.

Allowing practitioners to use their clinical judgement and treat as they normally would in 'real-world' practice is common in pragmatic trials, and this is sometimes known as the 'black box' treatment approach. It has the advantage of good generalizability to everyday practice (external validity), but the disadvantage of not having standardization between practitioners and not being able to define the active constituent(s) of the treatment. In contrast, a standardized protocol - using a predetermined technique or group oftechniques - has good internal validity and repeatability, but poorer external validity (it does not represent what actually occurs in clinical practice). The definition of OMT used in this study best represents real-world osteopathic practice,  $^{9,19,20}$  so the results of this review are more likely to be applicable to osteopaths in practice.

Therefore, our inclusion criteria were RCTs of OMT for chronic nonspecific neck pain where the

treating practitioner was an osteopath or osteopathic physician who used clinical judgement to determine the treatment performed. Only studies where an effect size could be assigned to the OMT intervention were considered. If co-interventions were used, they also had to be performed in the control group. Studies were excluded if they used an intervention of a single manual technique, such as high-velocity manipulation.

# Types of comparisons

Studies with any type of comparison intervention (e.g., manual therapy, usual care, sham treatment, untreated) were included.

# Types of outcome measures

Only patient-reported outcome measures were evaluated.

# Primary outcomes

The primary outcomes were pain and functional status. Pain was measured by visual analogue scale (VAS), numeric rating scale (NRS), or the McGill Pain Questionnaire. Studies measured functional status using validated neck disability questionnaires, such as the Neck Disability Index.

#### Secondary outcome

This outcome included any kind of adverse event.

## Data sources and searches

A systematic literature search was performed in March 2014 in the following electronic databases: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, PEDro, OSTMED.DR, and Osteopathic Web Research. The following search terms were used: neck pain, cervical pain, cervicalgia, neck ache, cervicobrachial neuralgia, cervicodynia, torticollis, atlanto-occipital joint, thoracic outlet syndrome, osteopathic manipulative treatment, OMT, and osteopathic medicine. A search strategy for one of the databases is provided in Table 1. In addition to the listed databases, an ongoing trial database was also screened (metaRegister of Controlled Trials http://controlled-trials.com/ mrct/). Our search was supplemented by citation tracking of the identified trials and a manual search of the reference lists for all relevant papers that were not listed in the electronic databases. There were no language or date restrictions.

#### Table 1Search strategy for MEDLINE database.

- 1. randomized controlled trial[Publication Type]
- 2. controlled clinical trial[Publication Type]
- 3. randomized[Title/Abstract]
- 4. placebo[Title/Abstract]
- 5. randomly[Title/Abstract]
- 6. trial[Title/Abstract]
- 7. groups[Title/Abstract]
- 8. or/1-7
- 9. cervicalgia[Title/Abstract]
- 10. neck pain[mh]
- 11. neck ache[Title/Abstract]
- 12. neck adj pain
- 13. cervical pain[Title/Abstract]
- 14. cervicobrachial neuralgia[Title/Abstract]
- 15. whiplash[Title/Abstract]
- 16. torticollis[Title/Abstract]
- 17. atlanto-occipital joint[Title/Abstract]
- 18. thoracic outlet syndrome[Title/Abstract]
- 19. cervicodynia[Title/Abstract]
- 20. or/9-19
- 21. 8 and 20
- 22. osteopathic medicine[MeSH Terms]
- 23. manipulation, osteopathic[MeSH Terms]
- 24. OMT[Title/Abstract]
- 25. or/22-24
- 26. 21 and 25

# Data collection and analysis

## Study selection

Two of the authors independently screened titles and abstracts of the studies identified by our search strategy. Potentially eligible studies were read in full text and independently evaluated for inclusion in the current review.

#### Data extraction and quality assessment

Two of the authors of the current review independently extracted data from identified studies using a standardized data extraction form.<sup>21</sup>

## Dealing with missing data

If the article did not contain sufficient information, the authors of the article were contacted for additional information. Some authors were asked for more detail on inclusion criteria, treatment frequency, outcome data, and adverse events. When standard deviations (SDs) were not reported, we estimated these from the confidence intervals (Cls) or other measures of variance, when possible.

## Assessment of heterogeneity

Heterogeneity refers to the variation in study outcomes between studies and is useful for the interpretation of meta-analysis results. Assessment of heterogeneity was based on the calculation of  $I^2$ . The Cochrane Collaboration<sup>21</sup> provides the following interpretation of  $I^2$ : 0% to 30%, might not be important; 30% to 60%, may represent moderate heterogeneity; 50% to 90%, may represent substantial heterogeneity; and 75% to 100%, considerable heterogeneity.

# Unit of analysis issues

In cases where 3 or more interventions were evaluated in a single study, we analysed each pairwise comparison separately. In these instances, the total number of participants in the OMT intervention group was divided evenly to be compared to each of the comparison groups.

#### Assessment of Risk of Bias

The methodological quality of the studies included in the review was assessed using the Risk of Bias tool from the Cochrane Back Review Group.<sup>22</sup> Discussion and consensus were used by the authors of the current review to resolve disagreements about the methodological quality of the RCTs assessed in the current review. The Risk of Bias criteria included assessment of randomization, blinding, baseline comparability between groups, patient compliance, and dropout rates, and each criterion was scored as low risk, high risk, or unclear. In line with recommendations from the Cochrane Back Review Group,<sup>22</sup> studies were rated as low risk when at least 6 criteria were met and the study had no serious flaws, such as a substantial dropout rate or major imbalance of participant characteristics at baseline. A dropout rate of greater than 50% was defined as a serious flaw, and this data would be excluded from quantitative analysis. When information was missing from the reviewed studies and the authors could not be contacted or when the information was no longer available, the criteria were scored as unclear.

# Measures of treatment effect

Data for the meta-analysis was analysed using Review Manager (RevMan, Version 5.3., Nordic Centre, http://ims.cochrane.org/ Cochrane revman). For measurements of pain from the included studies, the VAS or NRS scores obtained following completion of the treatment period were converted to a 100-point scale, and the mean difference (MD) with 95% CIs was calculated in a random effects model. For functional status, the standard mean difference (SMD) was also calculated in a random effects model. For the metaanalysis, the first measure point after the last treatment in each of the studies was used, which were at 6 weeks for one study<sup>23</sup> and 11 weeks for

the other 2.<sup>24,25</sup> Two studies<sup>24,25</sup> also reported follow up scores at 3 months, but given only 2 were available this data was not included in the meta-analysis.

#### Assessment of clinical relevance

Assessment of clinical relevance was made using the recommendations of the Cochrane Back Review Group.<sup>22</sup> Therefore, we defined a small effect as MD less than 10% of the pain scale (e.g., 10 mm on a 100-mm VAS) and SMD or *d* scores less than 0.5. A medium effect was defined as MD 10% to 20% of the scale and SMD or *d* scores from 0.5 to 0.8. A large effect was defined as MD greater than 20% of the scale and SMD or *d* scores greater than 0.8.<sup>22</sup>

#### Data synthesis

The overall quality of the evidence for each outcome in the included studies was assessed using the GRADE approach,<sup>26,27</sup> as recommended by the updated Cochrane Back Review Group method guidelines.<sup>22</sup> The GRADE approach specifies 4 levels of quality, high, moderate, low and very low, and the highest rating is given for RCT evidence. Authors of systematic reviews can downgrade this level of evidence to moderate, low, or even very low quality evidence, depending on the evaluation of guality of the evidence for each outcome against 5 key domains. The key domains are (1) limitations in design, (2) inconsistency of results, (3) indirectness (i.e., generalizability of the findings), (4) imprecision (downgraded when the total number of participants is less than 400 for each continuous outcome), and (5) other (such as publication bias).

For the current review, the following definitions for quality of evidence were followed. For high quality, further research was very unlikely to change our confidence in the estimate of effect. High guality evidence also had consistent findings in at least 75% of RCTs with no limitations in the study design and no known or suspected reporting biases. For moderate quality, further research was likely to have an important impact on confidence in the estimate of effect and may have changed the estimate; one of the domains was not met. For low quality, further research was very likely to have an important impact on confidence in the estimate of effect and was likely to change the estimate; two of the domains were not met. For very low quality, there was great uncertainty about the estimate; three of the domains were not met. For no evidence, no RCTs were identified that addressed the outcome.

#### Results

#### **Included studies**

The search strategy of the current review identified 299 studies (Fig. 1). Three studies<sup>23-25</sup> with 123 participants were included in the qualitative and quantitative analysis. Table 2 summarizes the important characteristics of the included studies. Two of the studies came from Germany<sup>24,25</sup> and 1 from Italy.<sup>23</sup> All included studies reported on pain, but only 2<sup>23,24</sup> reported functional status.

#### **Excluded studies**

Fifteen of the 18 identified studies were excluded from our review (Fig. 1). In 6 studies, the treatment was not an osteopathic treatment.<sup>28–33</sup> Three studies did not use RCT methodology,<sup>34–36</sup> and 2 studies focused on neck pain as a result of whiplash injury.<sup>37,38</sup> In another 2 studies, we could not differentiate neck pain results from back pain results.<sup>39,40</sup> Finally, 1 study examined asymptomatic participants,<sup>41</sup> and another focused on acute neck pain.<sup>42</sup>

# **Risk of Bias**

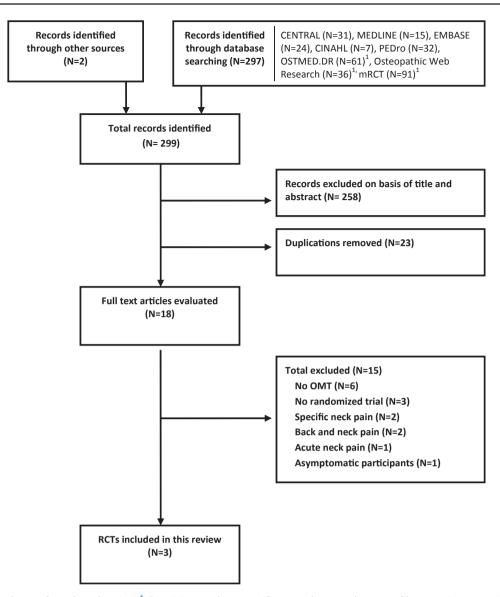
All of the included studies in the meta-analysis had high internal validity (low risk of bias) (Table 3).

#### Effect of interventions

Results are presented in the forest plots (Figs. 2 and 3) and in Table 4. Three studies with 123 participants were analysed for the effect of OMT for pain in chronic nonspecific neck pain. Two studies reported a significant effect on pain in favour of OMT, 23,25 and one study reported a nonsignificant effect in favour of OMT for current pain, although that study reported a significant effect in favour of OMT for 'average' pain.<sup>24</sup> For pain, the weighted mean baseline in the intervention group was 41.63 mm. There was moderatequality evidence (downgraded due to imprecision because there were fewer than 400 participants) that OMT had a statistically significant and clinically relevant effect on pain relief (MD: -13.04, 95% CI: -20.64 to -5.44) (Fig. 2 and Table 4).

Analysis of functional status was based on 2 studies<sup>23,24</sup> with a total of 65 participants. Both studies reported a significant effect in favour of OMT for functional status associated with pain.

# **ARTICLE IN PRESS**



**Fig. 1** Flowchart of study selection.<sup>1</sup> Sensitive and unspecific search, no adequate filter options possible. Abbreviations: mRCT, metaRegister of Controlled Trials; OMT, osteopathic manipulative treatment; RCT, randomized controlled trial.

There was moderate-quality evidence (downgraded due to imprecision because there were fewer than 400 participants) of a non-significant difference in favour of OMT (SMD: -0.38, 95% CI: -0.88 to 0.11) (Fig. 3 and Table 4).

#### Adverse events

Only 1 of the 3 studies reported on adverse events. Schwerla et al.<sup>24</sup> stated that no serious adverse events were reported during the treatment period although transient minor events, such as tiredness on the day of treatment and short-term aggravation of symptoms in other 'familiar' regions, were noted. The other 2 studies<sup>23,25</sup> did not report on

adverse events. In personal communications, the authors of these studies indicated that no adverse events occurred.

# Discussion

To our knowledge, the current review is the first systematic review with meta-analyses to examine the effect of OMT for chronic nonspecific neck pain. The included studies had to use an osteopathic approach where clinical judgement was used to individualize the treatment to each patient instead of using a single technique or predetermined set of techniques. Our analyses found

Author/Year Country	Tempel 2008 Germany	Schwerla 2008 <sup>a</sup> Germany	Mandara 2010 <sup>a</sup> Italy
Study design	RCT	RCT	RCT
Aim of the study	To assess the effectiveness of whether osteopathic treatment influences the pain of patients with chronic nonspecific neck disorder in comparison to physiotherapy	Assessment of OMT efficacy for chronic nonspecific neck pain	To investigate the effects of OMT plus standard care on self- reported pain and disability.
Duration of pain Reported inclusion/	At least 3 months yes/yes	At least 3 months yes/yes	At least 3 months yes/yes
exclusion criteria Outcome Measurement	1. VAS, 2. Duration of pain, 3. Frequency of pain, 4. SF-36, 5. Nordic questionnaire	<ol> <li>NRS of actual pain, average pain, and worst pain, 2. Northwick Park Pain Questionnaire, 3. Nordic Questionnaire, 4. SF-36, 5. Osteopathic examination form, 6. Medication questionnaire and diary</li> </ol>	1. VAS, 2. Neck disability index (Italian version)
No. of patients (rand.)/ Dropouts	60/2	41/4	28/8
No. of patients/mean age			
a. Intervention	a = 31/038	a = 23/042	a = 13/050
b. Control	b = 29/ø 42	b = 18/ø 45	b = 15/ø 50
Treatment (No.)			
a. Intervention	a = OMT (5)	a = Sham ultrasound (9) + OMT (5)	a = OMT (6) + standard care
b. Control	b = Physiotherapy (9–18)	b = Sham ultrasound (9)	b = Sham manipulatior (6) + standard care
Period	11 weeks	11 weeks	6 weeks
Follow up	After 3 months	After 3 months	
Authors conclusion	"Five osteopathic treatments over 10- week period could cause a clinically relevant influence on pain and quality of life in patients with chronic neck disorders."	"The results of this first rigorous randomized controlled trial seem to confirm previous empirical findings, and are in favour of an osteopathic treatment of CNP as a method with long-term effects "	"OMT added to standard care was able to significantly reduce neck pain and disability compared to SMT. The effect of the treatment seems to be dependent on the number of manipulative sessions"

CNP = Chronic neck pain; NRS = Numeric rating scale; NS = Not specified; SMT = Sham manual treatment; VAS = Visual analogue scale pain.

<sup>a</sup> Published and unpublished data.

significant effects for pain of a clinically relevant magnitude according to the criteria recommended by the Cochrane Collaboration.<sup>22</sup> The MD score was 13.04, which means that a change of 13.04 mm occurred on the 100 mm VAS scale. This change was greater than the minimal clinically important

difference and represents an improvement of 31% in relation to the baseline score. An MD from 10 to 20 on this scale is interpreted as a medium clinical effect, so the change in neck pain represents improvement that is likely to be clinically meaningful.<sup>22,43</sup> Our analysis of effect for functional

Table 3	Table 3 Risk of Bias in the included studies.	ne included s	tudies.									
Study	Randomization? Allocation Patient Care concealed? blinding? provi blind	Allocation Patient Care Outcome Drop-outs concealed? blinding? provider assessor described blinding? <sup>a</sup> blinding? <sup>b</sup> and acceptable	Patient blinding?	der ing?ª	Care Outcome Drop provider assessor desci blinding? <sup>a</sup> blinding? <sup>b</sup> and acce	2	Free of Groups Co- selective similar inte outcome at avoi reporting? baseline? or s	Groups similar at baseline?	Free of Groups Co- selective similar intervention outcome at avoided reporting? baseline? or similar?	Compliance Intention- Similar acceptable? to-treat timing analysis? of outco assessm	Intention- to-treat analysis?	Intention- Similar to-treat timing analysis? of outcome assessment?
	1	2	3	4	5	6	7	8	6	10	11	12
Schwerla LR 2008	LR	LR	HR	HR	HR	LR	LR	LR	LR	nc	HR	LR
Tempel 2008	LR	LR	HR	H	뜻	LR	LR	nc	LR	nc	HR	LR
Mandara 2010	LR	LR	nc	HR	nc	光	LR	СC	LR	LR	HR	LR
Abbreviatio <sup>a</sup> In manu <sup>b</sup> For pat	Abbreviations: HR, high risk of bias; LR, low risk of bias; UC, unclear. <sup>a</sup> In manual therapy studies, blinding is not possible. <sup>b</sup> For patient-reported outcomes, a low risk of bias is only possible if there is a low risk of bias for participant blinding.	f bias; LR, low blinding is not mes, a low ris	risk of bias t possible. k of bias is c	; UC, unclear only possible	r. if there is a	low risk of bi	as for partici	ant blindin	c'n			

status found a non-significant difference in favour of OMT, but this effect was not deemed to be clinically significant.

The risk of bias in the included 3 studies was assessed as low since all of them met at least 6 of the Risk of Bias criteria and had no serious flaws. None of the studies had a high risk of bias in the randomization and allocation procedures, but all had problems with the 3 blinding criteria. In manual therapy studies, blinding is typically an issue because patients tend to be aware when manual treatment is performed (versus sham, standard care or no treatment) and practitioners cannot be easily blinded to the treatment intervention they deliver.

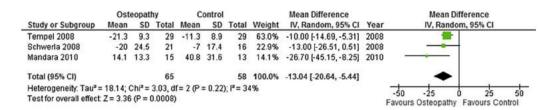
Although the current review is limited by the small number of included studies, the treatment effects appeared to compare favourably with the effects of other treatments from previously published systematic reviews.44-49 However, direct comparison of the relative effectiveness of OMT with other interventions commonly offered to patients with neck pain is not possible because of the different comparison groups in the studies of the current review and in other reviews. In the current review, the comparison groups were heterogeneous, and the studies compared OMT and sham ultrasound to sham ultrasound alone,<sup>24</sup> OMT to physiotherapy,<sup>25</sup> and OMT with standard care to sham manipulation with standard care.<sup>23</sup> The current authors hope that a growing number of studies in the near future will allow grouping of comparison interventions for estimation of the effect of OMT compared to specific interventions.

Statistical heterogeneity refers to the variation in study outcomes between studies and is useful for the interpretation of meta-analysis results. Assessment of heterogeneity was based on the calculation of  $I^2$ , as recommended by the Cochrane Collaboration.<sup>21</sup> For the outcome of pain,  $I^2$  was 34%, which can be interpreted as representing moderate heterogeneity. For functional status,  $I^2$ was 0%, which represents no or unimportant heterogeneity. Although the studies were small, which typically increases the likelihood of heterogeneity, substantial heterogeneity appeared not to be a major concern in either of the outcomes.

In one Cochrane review and meta-analysis, Gross et al.<sup>44</sup> compared the evidence of effectiveness of manipulation and mobilization for neck pain. The authors found some immediate- or shortterm pain relief with cervical manipulation or mobilization alone, but these benefits were not maintained over the long term. Further, moderatequality evidence suggested that cervical manipulation and mobilization produced similar effects

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**Fig. 2** Osteopathic manipulative treatment for chronic nonspecific neck pain. Outcome: pain. Abbreviations: CI, confidence interval; SD, standard deviation.

for pain and function. Evidence also supported the use of thoracic manipulation alone for immediate pain relief and improvements in function. In another review, Cross et al.<sup>45</sup> found that thoracic spine thrust manipulation seemed to provide short-term improvement in patients with acute or subacute mechanical neck pain, but they concluded that the evidence was weak. The review by Gross et al.<sup>44</sup> included 27 studies and 1522 analyzed patients, which represents a greater number of patients than in the current review. In another review,<sup>46</sup> the effectiveness of massage for neck pain was uncertain because only very lowlevel evidence was found that massage techniques were more effective than control or placebo treatments in improving function and tenderness.

The addition of exercises to manual therapy treatment appears to be beneficial. In a review of exercises for neck disorders. Kay et al.<sup>47</sup> found low-to-moderate guality evidence supporting the use of specific cervical and scapular stretching and strengthening exercises for chronic neck pain immediately post-treatment and medium term. Further, according to a recent review,<sup>48</sup> 2 highquality trials suggested a benefit from the addition of exercises to manual therapies. In a study by Miller et al.,<sup>49</sup> moderate-guality evidence was found for a combination of exercises and manual therapy for pain reduction over manual therapy alone and high-quality evidence was found for greater short-term pain relief, but no long-term differences were found for chronic neck pain. The authors also reported low-quality evidence for clinically important long-term improvements in functional status. In the current review, osteopaths used a variety of manual techniques according to their clinical judgement, but none of the technique descriptions in the included studies outlined the prescription of home stretching or strengthening exercises. Future studies should consider the addition of exercises to enhance the effectiveness of OMT.

The authors of the current review are not aware of other systematic reviews of OMT for neck pain.

However, reviews do exist for OMT of musculoskeletal pain<sup>13</sup> and low back pain.<sup>11,12,50</sup> In a recent comprehensive review of OMT for low back pain, Franke et al.<sup>12</sup> reviewed 15 studies and found moderate-quality evidence of a significant effect on pain relief and functional status in acute or chronic low back pain and in chronic nonspecific low back pain, and the effects appeared to be clinically significant. Further, the authors<sup>12</sup> found the effects of OMT appeared to have a larger effect on pain than functional status. This finding supports results from the current review, where the effects of OMT also appeared to more strongly influence pain than functional status.

The Cochrane Collaboration<sup>21</sup> recommends that authors of systematic reviews search for unpublished studies, and one of the included studies in the current review was found in the 'grey' literature as part of the proceedings from a conference.<sup>25</sup> Of the 2 other included studies, the study by Schwerla et al.<sup>24</sup> was published as a full paper, and the study by Mandara et al.<sup>23</sup> was published only as an abstract. Two of the included studies were from Germany<sup>24,25</sup> and one from Italy.<sup>23</sup> Given that there is variation in the use and emphasis of techniques and the style of practice throughout the world, it is unknown whether the treatment approaches used in these studies are comparable to the typical treatment approaches used by osteopathic physicians in the United States or by osteopaths in the United Kingdom, Australia, and elsewhere.

The delivery of OMT in each of the included studies was not standardized between practitioners, but it represented the practice approach typically used in private clinical practice since a range of manual techniques were used that required individual clinical judgement for each patient. Most of the studies provided an indication of the range of manual techniques used for OMT, but the exact interventions performed for each patient were generally unknown. For instance, OMT interventions in the included studies may have emphasized different manual treatment approaches, such as direct, indirect, visceral or

# Table 4 Summary of findings of included randomized controlled trials.

OMT compared to other interventions for chronic nonspecific neck pain

Outcomes	Illustrative comparative risks <sup>a</sup> (95% CI)		No. of participants	Quality of the	Comments
	Assumed risk Other interventions	Corresponding risk OMT	(studies)	evidence (GRADE)	
Pain Pain VAS Scale from 0 to 100 (worse pain)	The mean pain ranged across control groups from <b>24.4 to 36.9</b>	The mean pain in the intervention groups was <b>13.04 lower</b> (20.64 to 5.44 lower)	123 (3 studies)	$\oplus \oplus \oplus \ominus$ moderate <sup>b</sup>	This difference is statistically significant and clinically relevant
Functional status Disability Questionnaire (higher scores = worse function)	The mean functional status ranged across control groups from <b>27.2 to 35</b>	The mean functional status in the intervention groups was <b>0.38 standard</b> <b>deviations lower</b> (0.88 lower to 0.11 higher)	65 (2 studies)	$\oplus \oplus \oplus \oplus \oplus$ moderate <sup>b</sup>	This difference is not statistically significant and not likely to be clinically relevant
Adverse events	Not observed	Not estimable	123 (3 studies)		In the studies no adverse events were observed

GRADE Working Group grades of evidence:

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

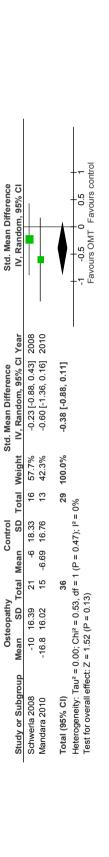
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.

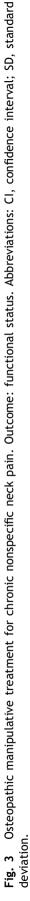
Abbreviations: CI, confidence interval; OMT, osteopathic manipulative treatment; VAS, visual analogue scale.

<sup>a</sup> The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

<sup>b</sup> Participants <400.

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cranial techniques.<sup>5</sup> Unfortunately, this lack of specific information did not enable us to identify whether responder and non-responder patient groups received different treatments or what were the most effective components of the OMT interventions for neck pain.

Few clinical guidelines for the treatment of neck pain exist, and because the osteopathic treatments included in the reviewed studies do not specify the particular techniques and advice, it is difficult to determine whether these treatments comply with available guidelines. In a guideline produced by the American Physical Therapy Association, Childs et al.<sup>51</sup> recommend cervical thrust manipulation and mobilization procedures. particularly if combined with exercises, as well as thoracic spine thrust manipulation. Given that OMT often includes spinal manipulation directed at both symptomatic and anatomically related regions, it is likely that treatment complied with these limited guidelines.

The major limitations of the current review were the small number of available studies and the small sample sizes in those studies. The 3 included studies had sample sizes of 60, 41, and 28 participants. Therefore, the total number of participants in the current review was under 400 participants, which creates imprecision and requires downgrading the level of evidence according to the GRADE criteria.<sup>26,27</sup> In addition, there were different comparison groups in the included studies, such as active treatment with physiotherapy<sup>25</sup> or placebo controls using sham manipulation<sup>23</sup> and sham ultrasound.<sup>24</sup>

# Conclusion

To our knowledge, the current systematic review is the first to review studies to assess the effectiveness of OMT in the management of chronic nonspecific neck pain. The studies we reviewed generally had a low risk of bias but had small sample sizes of patients and different comparison treatments. Our results suggested that OMT improved pain in chronic nonspecific neck pain in a clinically meaningful way, but the improvement in functional status seemed to be small and not likely to be clinically meaningful. Given the small sample sizes, different comparison groups in the different studies, and lack of long-term measurement in the included studies, larger, highquality RCTs with robust comparison groups are needed to provide firm conclusions regarding the effectiveness of OMT for chronic neck pain.

# Competing interest, funding source, and conflict of interest statement

The authors declare that they have no competing interests. This research received no grant from any funding agency in the public, commercial, or notfor-profit sectors. Both HF and GF are osteopaths.

# Ethical statement

The study was a systematic review. It did not involve experimentation on human subjects and therefore did not require approval from an Institutional Ethics committee. The study met the requirements of systematic reviews detailed by the PRISMA statement.

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