

Narrative Systematic Review of studies of NSAIDS and LBP

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Background: Spinal manipulation therapists such as chiropractors emphasise, they are quintessential primary carers of low back pain (LBP) sufferers however, the most common and primary treatment in managing this pain are analgesics.

Introduction: This systematic narrative review aims to answer the clinical question regarding what treatment intervention is suitable in pain management in both adults and geriatric populations suffering from either subacute, acute or chronic LBP with the interventions being high velocity low amplitude spinal manipulation therapy (HVLA-SMT) compared to over the counter (OTC) medications such as non-steroidal anti-inflammatory drugs (NSAIDS) or muscle relaxants.

Method: An online search through six databases yielding 236 possible results used with key terms and exclusion and inclusion criteria for relevance to the clinical question leaving for a filtered twenty research papers consisting of nine randomised control trials, five systematic reviews, one observational study, one cross sectional study, one case study and three professional guidelines which were graded for quality control against clinical appraisal and risk of bias tools.

Results: The published literatures LBP outcome measures of pain indexes were extrapolated into comparable tables and where assessed concluding with mixed results regarding the efficacy of pain management of HVLA-SMT when compared to OTC medications being either minimal, same or none.

Conclusion: Although the vast majority of data demonstrates SMT as having a similar pain management effects as OTC medication a necessary review is needed into the quality of experiments conducted as the bias tools have demonstrated many inconsistencies with how data was obtained and handled.

Indexing terms: Chiropractic; SMT; LBP; NSAIDS; OTC; geriatrics

Introduction

The objective of this review is to address the following clinical question regarding what treatment intervention is the most effective in pain management either HVLA-SMT or OTC medications such as NSAIDS or muscle relaxants in 20-65 year olds suffering from either subacute, acute or chronic LBP.

The clinic question is quintessential as musculoskeletal disorders are the second leading cause of disease burden worldwide led by LBP (1) affecting adults with the prevalence rates ranging from 32% and as high as 58% (2) accounting for 4.1% of Australia's disease burden being the second leading cause of total disease according to a Australian government fact sheet (3) with a 2017-2018 Australian Bureau of Statistics' National Health Survey stating that back

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pain affects 4-million Australians or 16.4% of the population. (4) Consequently, this is the most common musculoskeletal condition debilitating 45-64y Australians out of the workforce causing a loss of productivity (5) and reducing the Australian GDP by AU\$3.2 billion per annum. (6)

LBP can be divided either as acute LBP (pain experienced over <4 weeks), subacute LBP (4 - 12 weeks), and chronic LBP (>12 weeks) (7) with the prevalence of chronic LBP in adults increasing more than 100% in the last decade and continuing to dramatically increase in the middle aged to geriatric population with no specific prevalence in sex or ethnicity. (5) The exact cause of LBP can be broad with pain deriving from many anatomical sources including muscle hypertonicity/hypotonicity, nerve roots, fascial structures, joints, bones, intervertebral discs, and referred pain from other structures. (5)

Currently, there is an estimated 25% of adults worldwide prescribed with OTC analgesics medication in treatment for their LBP (2) where in 2018, the most widely taken medications in Australia were general or OTC medications consisting of *Aspirin*, *Panadol*, *Voltaren* and *Nurofen* with 77.3% of Australians ingesting these OTC medications for pain related symptoms including back pain. (8) The second line of recommended care for managing LBP is ingesting NSAIDs, *codeine* then SMT or other interventions. (9)

A similar systematic narrative review by Rothberg et al published in 2017 (10) in the *American Journal of Emergency Medicine* aimed to compare the efficacy of several complementary therapies including yoga, massage, exercise and SMT with addition to standard medical therapy consisting of either NSAIDs or skeletal muscle relaxants in patients suffering from non-chronic and non-radicular LBP. Their conclusion stated there was insufficient evidence that all the mentioned complementary therapies were non-beneficial as they failed to show benefit vs medical therapy alone. The limitation of this study was their research strategy as the data they required did not tailor to their specific research goal in identifying a complementary therapy being a useful adjuvant to patients already participating in standard medical therapy among their mentioned population. Their strict research goal disabled their options as from their 195 discovered research articles from their chosen databases only two randomised control trials (RCT's), (11, 12) met their criterion rendering it insufficient enough evidence where SMT research is already limited.

This review is essential and different to the Rothberg et al (10) review as the topic explored is investigating the effectiveness of evidenced based HVLA-SMT to already established usual medical care OTC medications in pain reduction in patients by assessing and comparing published literature outcomes regarding reduction in pain symptoms in separate intervention groups which will advance an ideological understanding that there are possible evidence based, effective, safe, non-pharmacologic pain management options such as HVLA-SMT being one of the many vitality alternatives (13) that can be considered and possibly implemented as primary care where OTC dependency (14) and upgrading to opioids is statistically on the rise. (2)

Methods

Search strategy

Answering the clinical question an online grey and Boolean literature review search strategy was conducted on six search engine databases including, PubMed, CINAHL, Google Scholar, Cochrane, International Journal Of Osteopathic Medicine and Index Literature of Chiropractic and Manual Therapies from early March to early May 2020.

The Boolean operators [AND] and [OR], and [NOT], in conjunction with the key words and mesh terms [chiropractic], [osteopathic], [spinal manipulation therapy], [SMT], [adults], [geriatric], [elderly], [subacute], [acute], [chronic], [low back pain], [LBP], [over the counter], [analgesics], [pain medication], [NSAIDs], and [muscle relaxants] to filter suitable journal articles.

Advanced results consisted of 236 total publications across six databases where reference lists of utilised articles were harvested for relevant research citations with additional refinement using the inclusion and exclusion criteria below was indoctrinated aiding in the removal of duplications or

unrelated research papers during phase one screening. The title, abstracts, methodologies and conclusions were analysed for specificity and thematic relevance to the clinical question in phase two screening leaving the final twenty research papers. The final research papers have been recorded into a modified 2009 Prisma flow diagram (15) adapted from the <http://prisma-statement.org/> which can be observed in Appendix A. The twenty research papers were then graded with its adequate clinical appraisal and risk of bias tools to determine its validity and the accuracy of each research review.

Inclusion Criteria

Peer reviewed journals published in English from the years of 2000-2020 with the mentioned keywords that compared the efficacy of HVLA-SMT to OTC with the literature's outcome measures containing data regarding pain. HVLA-SMT performed by an SMT therapist including chiropractors, osteopaths or physiotherapists on participants aged 20 to 65 years of age suffering either from subacute, acute or chronic LBP was included. OTC medications that consisted only of NSAIDS or muscle relaxants prescribed by medical professionals and any publications that assessed other alternative treatments as well as HVLA-SMT were also included.

Exclusion Criteria

Non-English research publications that were non-peer reviewed, prior to the year 2000 whose participants were animals or contained unspecified subject age or unspecified chronicity of LBP was excluded. HVLA-SMT treatment by a non-licensed spinal manipulation therapist or prescription of other medications that was not either NSAIDS or muscle relaxants or was not considered OTC medication such as opioids that were prescribed by a non-medical professional was excluded.

Discussion

LBP is a common worldwide problem with primary intervention strategies recommending the consumption of OTC medications for its pain management. The purpose of this systematic review is to compare which treatment intervention is the most effective in managing pain in adults and within the geriatric community.

The final twenty research papers were evaluated through the risk of bias and clinical appraisal tools to determine their quality, accuracy and validity. Nine research articles (11, 12, 13, 16, 17, 18, 19, 20, 21) were RCT's with the clinical appraisal tool used was the 2010 CONSORT checklist (22) adapted from www.consort-statement.org which is given as Appendix B. Five articles (10, 23, 24, 25, 26) were systematic reviews with a 2009 Prisma checklist (27) adapted from www.prisma-statement.org given as Appendix C. One article (28) was an observational study using the tool STROBE checklist (29) adapted from <http://www.strobe-statement.org> given in Appendix D. One article (30) was a cross sectional study using the STROBE checklist for cross-sectional studies (31) also adapted from www.strobe-statement.org observed in appendix E. One (1) was a case study using the CEBMa checklist (32) adapted from www.cebma.org given as Appendix F. The last three articles (7, 33, 34) were professional guidelines using the AGREE checklist (35) adapted from <http://www.agreetrust.org> given as Appendix G.

The highest scoring RCT according to the 2010 CONSORT checklist was published by Hancock et al (12) with the lowest scoring RCT published by Golstein et al (17) with the limitations of these studies appearing as red blocks (meaning an absence of specified criteria in the appraisal tool) where a pattern of main insufficiencies include the type of randomisation with five articles (13, 16, 17, 18, 19) omitted if blocking was done to reduce the bias of patient allocation. Unfair blinding or no blinding was another common issue present in six articles (13, 16, 17, 19, 20, 21) with authors acknowledging blinding was not possible due to ethical reasons (13, 21) or patients and researchers were blinded in the prescription of NSAIDS but no blinding was done with the SMT intervention group or if a questionnaire was taken to determine if blinding was successful. (12) This was also similarly noticed where a secondary physician was blinded and was not aware if the primary physician was performing either a sham adjustment or SMT treatment where patients were blinded and unaware

but were not blinded when prescribed NSAIDS. (19) The remaining two articles only had a blinded group who recorded patient outcome measures (11, 20) and only one article (12) had both the registration number and details where the full protocol can be accessed where two articles (11, 20) only had registration numbers.

The highest scoring systematic review according to the 2009 PRIMSA checklist was published by Malanga et al (24) with the lowest scoring review published by McIntosh et al (25) with the main patterns of insufficiencies seen across the articles omitting an accessible reviewed full protocol in four articles (10, 24, 25, 26) essential to prevent bias data selection leading to absent results. Four articles (10, 24, 25, 26) omit sources of funding or funders (23, 24, 25) and omitted their full electronic search strategy of databases. These omissions can limit the mentioned research papers quality as this can attribute to accidental replicated data collection across databases, and exclusion of funding or funders is an organisational type of bias that may indicate ethically compromised science to satisfy the funding agency or people.

Observing the *Strobe* checklist for the observational study published by Prinsen et al (28) the main problems include an absent specific study size, any mention of sensitivity analyses, exposed or unexposed match studies, risks and funding. Similarly, the *Strobe* checklist for cross sectional studies for the cross sectional study published by Knauer et al (30) omitted how any bias was addressed, study size, missing data, summary measures or the inclusion of a flow diagram. Observing the *CEBMa* checklist for the observational study published by Goertz et al (1) the only issue was absent quality controls measures such as questionnaires to inquire patients if they were aware of the treatment they received felt either was a sham, placebo, real SMT or real prescription medication.

The highest scoring government guidelines according to the 2016 *Agree* checklist was published by Qaseem et al (7) and the lowest scoring was published by Tulder et al (34) with the main patterns of insufficiencies seen across the articles include absent names of participants, voting procedures, types of competing interest, or how competing interests could have influenced development of recommendations. (33, 34) An area that all three articles failed was the types of facilitators and barriers that considered recommendations. (7, 33, 34)

Overall, the common limitations across the literature include blinding, funding, registry, randomisation strategies, redundant publication of clinical trials, unfair group selection, absent data, possible duplication of results and selective reporting with outcome measures all leading to potential flawed research possibly affecting their outcome measures of pain management.

Results

The five systematic reviews concluded with mixed results due to limited and low-quality evidence, (23, 24, 25) insufficient data supporting the use of SMT combined with standard medical therapy (10) while intramuscular NSAIDS had similar outcomes in pain reduction as combined HVLA and soft tissue therapy. However, this may be attributed to the critical appraisal tool they utilised as stated by the authors which used the '*Jadad scale*' for grading their RCTS condemning it for being too simplistic and not mentioning allocation concealment procedures. (26)

Similarly, two published guidelines (7, 33) also concluded that alternative interventions including SMT had low quality evidence to support the use of its treatment in reducing LBP when compared to NSAIDS with moderate evidence to support muscle relaxants in managing LBP. (33) The second guideline indicates a strong recommendation that patients suffering from acute or subacute LBP should ingest NSAIDS or muscle relaxants with moderate quality evidence to support this claim rather than SMT which has low quality evidence (7). The third guideline (34) inconclusively concludes with its recommendations on SMT as previous research has demonstrated acute LBP had variation with results considering SMT as an therapeutic option in the first weeks of a LBP with the UK, New Zealand and Danish guidelines consider SMT as a useful treatment for acute LBP whereas Dutch, Australian and Israeli guidelines strongly advocate against SMT with acute LBP but consider it after 6 weeks of pain symptoms. This guideline also has strong evidence and recommends regular NSAIDS and muscle relaxants are important for managing acute LBP. (34)

Referring to Appendix H titled '*Summary Table of Pertinent Results from nine RCTS Including Pain Outcome Measures*', four (17, 18, 20, 21) out of the nine RCTS recorded their participants pain outcomes measures after a 24 week period using the self-administered *Roland-Morris* questionnaire (RMQ) a 24-point scale where the higher values indicated more pain. These articles concluded that there was a minor change in pain reduction after 24 weeks with mixed results revealing HVLA-SMT had little to no impact in their outcome measures of reduced pain when compared to NSAIDS (21) where the highest difference between two intervention groups average mean data was Δ 1.1 by Hondras et al. (20) Two RCT papers (12, 13) recorded their participants pain outcomes measures after a 4 week period using the numeric pain rating score (NPRS) with Δ 0.3 the highest difference by Hancock et al. (12) One research paper (11) used the 11-point box scale (BS-11) a self-administered questionnaire with 11-points ranging from 0 to 10 as their outcome measure over a two week period with higher values indicating more pain with a Δ 0.5 between the two intervention groups. Two research papers (16, 19) used the visual analogue scale (VAS) where participants record their severity of pain on 10-cm line with the difference of Δ 2 published by Giles et al (16) where the last RCT paper (19) differed from the rest of the RCTS as their comparator to HVLA-SMT was muscle relaxants where their difference in outcome measures was Δ 0.57 by Hoiriis et al (19).

Referring to Appendix I titled '*Summary Table of Pertinent Results from Three Published Literatures Including Pain Outcome Measures*', the observational study published by Prinsen et al (28) used a VAS to record participants pain severity after a 9 week period with the difference between the two intervention groups of Δ 0.11. The cross sectional telephone study published by Knauer et al (30) used a SF 12 physical component score (SF-12) after 3 months where a Δ 0.1 and the case study published by Goertz et al (1) used a NPRS after twelve weeks with a Δ 0.9 difference between the two intervention groups. Overall, these three studies concluded that only a small change in pain outcome measures occurred between a HVLA-SMT and OTC intervention group.

The evidence of pain reduction of SMT against OTC medication from across the literature has shown either little, same or no improvements with a broad range of outcome measures assessed to determine the validity of this cause and effect.

Conclusion

This review cannot conclusively judge regarding the initial clinical question as although the outcome measures of pain across the research literatures demonstrates SMT as either minimally, same or non-effective in managing LBP in either acute, subacute or chronic stages experienced in both adults and geriatric participants when compared to the specified OTC medications.

However, what can be strongly justified is the potential flawed evidence not related to lack of published literature but caused by various quality issues as shown in the clinical appraisal and risk of bias tools where the failures of the conducted research needs to be adequately addressed for a more justified conclusive answer concerning the initial clinical question.

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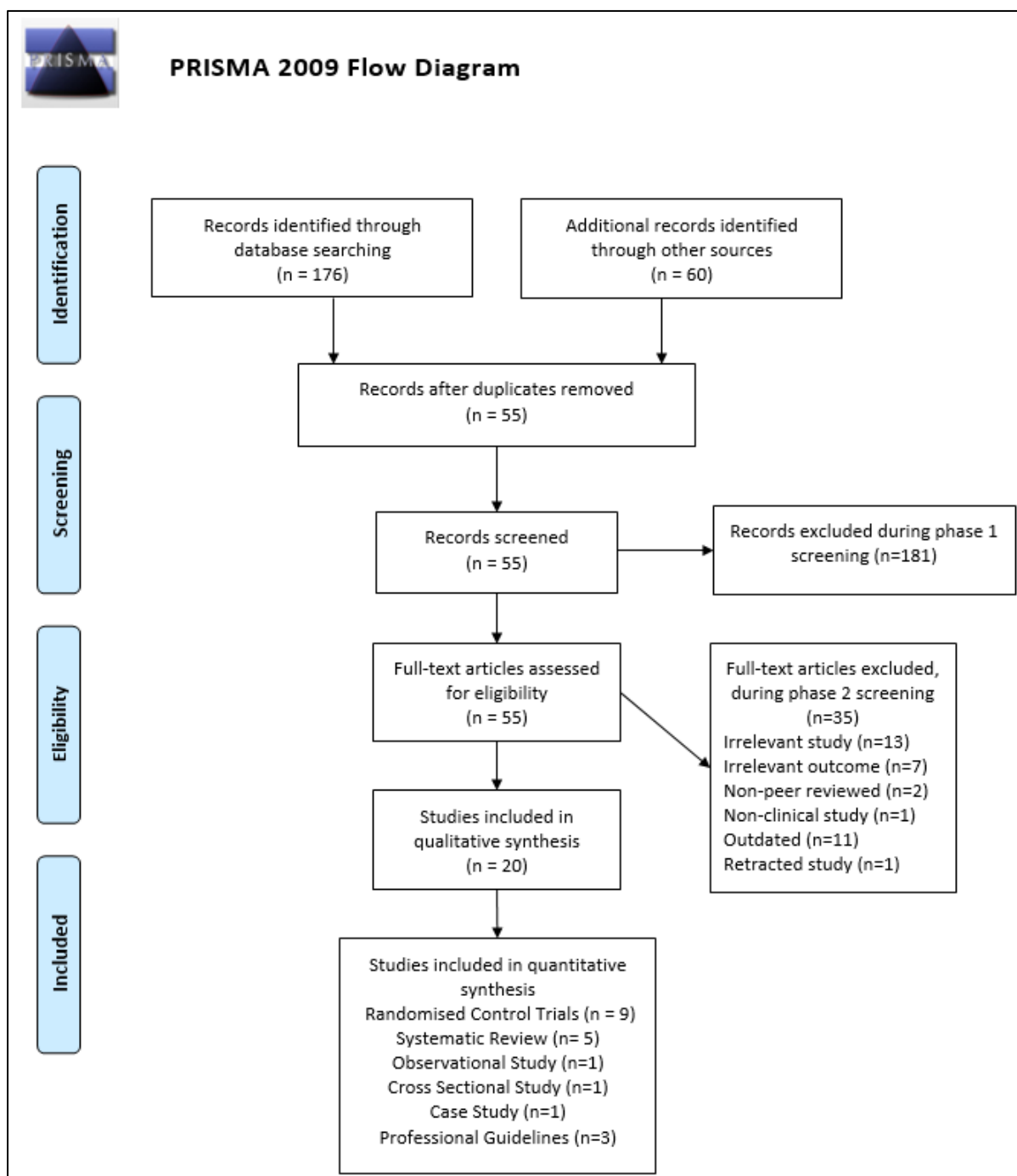
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Appendix A

PRISMA 2009 flow diagram



Appendix B
2010 CONSORT checklist

Randomised Control Trials		Giles. et al ⁽¹⁶⁾	Golde nstein et al (17)	Hanc ock et al ⁽¹²⁾	Heym ann et al (18)	Hoiri is et al ⁽¹⁹⁾	Hond uras et al (20)	Hur witz et al (21)	Juni et al (11)	Schni eder et al (13)
Title & Abstract	1a. Identification as a randomised trial in the title.									
	1b. Structured summary of trial design, methods, results, and conclusions.									
Introduction	2a. Scientific background and explanation of rationale									
	2b. Specific objectives or hypotheses									
Methods	3a. Description of trial design.									
	3b. Important changes to methods after trial commencement with reasons.									
	4a. Eligibility criteria for participants.									
	4b. Settings and locations where the data were collected									
	5. The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.									

Methods	6a. Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Green	Red	Green	Green	Red	Green	Green	Green	
	6b. Any changes to trial outcomes after the trial commenced, with reasons.	Green	Red	Green	Green	Red	Green	Green	Green	
	7a. How sample size was determined.	Red	Red	Green	Green	Green	Red	Red	Green	
	7b. When applicable, explanation of any interim analyses and stopping guidelines.	Red	Red	Red	Green	Red	Red	Red	Red	Green
	8a. Method used to generate the random allocation sequence.	Red	Green	Green	Green	Green	Green	Green	Green	Green
	8b. Type of randomisation; details of any restriction (such as blocking and block size).	Red	Red	Green	Red	Red	Green	Green	Green	Red
	9. Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned.	Red	Green	Green	Green	Green	Green	Green	Green	Green

Methods	10. Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions.	Red	Green	Green	Green	Green	Green	Green	Green
	11a. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	Red	Red	Green	Red	Red	Red	Green	Red
	11b. If relevant, description of the similarity of interventions.	Green	Green	Green	Red	Red	Green	Green	Green
	12a. Statistical methods used to compare groups for primary and secondary outcomes.	Green	Green	Green	Green	Green	Green	Green	Green
	12b. Methods for additional analyses, such as subgroup analyses and adjusted analyses.	Green	Green	Green	Green	Green	Green	Green	Green
	13b. For each group, losses and exclusions after randomisation, together with reasons.	Green	Green	Green	Green	Green	Green	Green	Green
	13b. For each group, losses and exclusions after randomisation, together with reasons.	Green	Green	Green	Green	Green	Green	Green	Green

Results	14 a. Dates defining the periods of recruitment and follow-up.																			
	14b. Why the trial ended or was stopped.																			
	15. A table showing baseline demographic and clinical characteristics for each group.																			
	16. For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups.																			
	17a. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval).																			
	17b. For binary outcomes, presentation of both absolute and relative effect sizes is recommended.																			
	18. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory.																			
	19. All important harms or unintended effects in each group (for specific guidance see CONSORT for harms).																			

Discussion	20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	Red	Green	Red	Green	Green	Green	Green	Green
	21. Generalisability (external validity, applicability) of the trial findings.	Green	Green	Green	Green	Green	Green	Green	Green
	22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	Green	Green	Green	Green	Green	Green	Red	Green
Other Information	23. Registration number and name of trial registry.	Red	Red	Green	Red	Red	Green	Red	Red
	24. Where the full trial protocol can be accessed, if available.	Red	Red	Green	Red	Red	Red	Red	Red
	25. Sources of funding and other support (such as supply of drugs), role of funders	Green	Red	Green	Green	Green	Green	Green	Green
Green = Present; Red = Absent									

Appendix C
PRISMA 2009 checklist

Systematic Review Publications		Chou et al⁽²³⁾	Malanga et al⁽²⁴⁾	McIntosh et al⁽²⁵⁾	Rotherberg et al⁽¹⁰⁾	Wong et al⁽²⁶⁾
Title	1. Identify the report as a systematic review, meta-analysis, or both.					
Abstract	2. Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.					
Introduction	3. Describe the rationale for the review in the context of what is already known.					
	4. Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).					
Method	5. Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.					
	6. Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.					
	7. Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.					
	8. Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.					
	9. State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).					

Method	10. Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.					
	11. List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.					
	12. Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.					
	13. State the principal summary measures (e.g., risk ratio, difference in means).					
	14. Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.					
	15. Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).					
	16. Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.					
	17. Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.					
18. For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.						

Results	19. Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Red	Red	Green	Red	Green
	20. For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Green	Green	Green	Green	Green
	21. Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Green	Green	Green	Green	Green
	22. Present results of any assessment of risk of bias across studies (see Item 15).	Red	Red	Green	Green	Green
	23. Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Red	Green	Green	Red	Green
	23. Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Red	Green	Green	Red	Green
Discussion	24. Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Green	Green	Green	Green	Green
	25. Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Green	Green	Green	Red	Red
	26. Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Green	Green	Green	Red	Red
	27. Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Green	Red	Red	Red	Red

Green = Present; Red = Absent

Appendix D
STROBE checklist

Observational Study Publication		Prinsen et al (28)
Title & Abstract	Indicate the study's design with a commonly used term in the title or the abstract	
	Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction	Explain the scientific background and rationale for the investigation being reported	
	State specific objectives, including any prespecified hypotheses	
Methods	Present key elements of study design early in the paper	
	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	
	For matched studies, give matching criteria and number of exposed and unexposed	
	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
	Describe any efforts to address potential sources of bias	
	Explain how the study size was arrived at	
	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
	Describe all statistical methods, including those used to control for confounding	
	Describe any methods used to examine subgroups and interactions	

Results	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Green
	Give reasons for non-participation at each stage	Green
	Consider use of a flow diagram	Green
	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Green
	Indicate number of participants with missing data for each variable of interest	Green
	Summarise follow-up time (eg, average and total amount)	Green
	Report numbers of outcome events or summary measures over time	Green
	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Red
	Report category boundaries when continuous variables were categorized	Red
	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Red
	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Green
Discussion	Summarise key results with reference to study objectives	Green
	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Green
	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Green
	Discuss the generalisability (external validity) of the study results	Green
Other	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Red
Green = Present; Red = Absent.		

Appendix E

STROBE cross-sectional checklist

Cross Sectional Literature		Knauer et al ⁽³⁰⁾
Title & Abstract	Indicate the study's design with a commonly used term in the title or the abstract.	
	Provide in the abstract an informative and balanced summary of what was done and what was found.	
Introduction	Explain the scientific background and rationale for the investigation being reported.	
	State specific objectives, including any prespecified hypotheses.	
Methods	Present key elements of study design early in the paper.	
	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	
	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	
	For matched studies, give matching criteria and number of exposed and unexposed.	
	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	
	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group.	
	Describe any efforts to address potential sources of bias.	
	Explain how the study size was arrived at.	
	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why.	
	Describe all statistical methods, including those used to control for confounding	
	Describe any methods used to examine subgroups and interactions.	
	Explain how missing data were addressed.	
	If applicable, describe analytical methods taking account of sampling strategy.	
Describe any sensitivity analyses.		

Results	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed.	Green
	Give reasons for non-participation at each stage.	Green
	Consider use of a flow diagram.	Red
	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders.	Green
	Indicate number of participants with missing data for each variable of interest.	Red
	Report numbers of outcome events or summary measures.	Red
	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included.	Green
	Report category boundaries when continuous variables were categorized.	Green
	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.	Green
	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses.	Green
	Summarise key results with reference to study objectives.	Green
Discussion	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	Green
	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	Green
	Discuss the generalisability (external validity) of the study results.	Green
Other	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.	Green
Green = Present; Red = Absent.		

Appendix F
CEBMA checklist

Case Study Literature	Goertz et al ⁽¹⁾
1. Did the study address a clearly focused question / issue?	
2. Is the research method (study design) appropriate for answering the research question?	
3. Are both the setting and the subjects representative with regard to the population to which the findings will be referred?	
4. Is the researcher's perspective clearly described and taken into account?	
5. Are the methods for collecting data clearly described?	
6. Are the methods for analyzing the data likely to be valid and reliable? Are quality control measures used?	
7. Was the analysis repeated by more than one researcher to ensure reliability?	
8. Are the results credible, and if so, are they relevant for practice?	
9. Are the conclusions drawn justified by the results?	
10. Are the findings of the study transferable to other settings?	
Green = Present; Red = Absent.	

Appendix G

AGREE checklist

Guideline Publications		Quaseem et al ⁽⁷⁾	Stockenhall et al ⁽³³⁾	Tulder et al ⁽³⁴⁾
Objectives	1. Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.).			
	2. Expected benefit(s) or outcome(s).			
	3. Target(s) (e.g., patient population, society).			
Questions	4. Target population.			
	5. Intervention(s) or exposure(s).			
	6. Comparisons (if appropriate).			
	7. Outcome(s).			
Population	8. Health care setting or context.			
	9. Target population, sex and age			
	10. Clinical condition (if relevant).			
	11. Severity/stage of disease (if relevant).			
	12. Comorbidities (if relevant).			
Group Membership	13. Excluded populations (if relevant).			
	14. Name of participant.			
	15. Discipline/content expertise (e.g., neurosurgeon, methodologist).			
	16. Institution (e.g., St. Peter's hospital).			
	17. Geographical location (e.g., Seattle, WA).			
Target Population & Views	18. A description of the member's role in the guideline development group.			
	19. Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review, of values and preferences).			
	20. Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups).			
	21. Outcomes/information gathered on patient/public information.			
	22. How the information gathered was used to inform the guideline development process and/or formation of the recommendations.			

Target Users	23. The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators).			
	24. How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care).			
Search Methods	25. Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL).			
	26. Time periods searched (e.g., January 1, 2004 to March 31, 2008).			
	27. Search terms used (e.g., text words, indexing terms, subheadings).			
	28. Full search strategy included (e.g., possibly located in appendix).			
Evidence Selection Criteria	29. Target population (patient, public, etc.) characteristics.			
	30. Study design .			
	31. Comparisons (if relevant).			
	32. Outcomes.			
	33. Language (if relevant).			
	34. Context (if relevant).			
Strength & Limitations of the Evidence	35. Study design(s) included in body of evidence.			
	36. Study methodology limitations (sampling, blinding, allocation concealment, analytical methods).			
	37. Appropriateness/relevance of primary and secondary outcomes considered.			
	38. Consistency of results across studies.			
	39. Direction of results across studies.			
	40. Magnitude of benefit versus magnitude of harm.			
	41. Magnitude of benefit versus magnitude of harm.			
Formulation of Recommendations	42. Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered)			
	43. Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures).			
	44. How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote).			

Consideration of Benefits & Harm	45. Supporting data and report of benefits			
	46. Supporting data and report of harms/side effects/risks.			
	47. Reporting of the balance/trade-off between benefits and harms/side effects/risks			
	48. Recommendations reflect considerations of both benefits and harms/side effects/risks.			
Link Between Recommendations & Evidence	49. How the guideline development group linked and used the evidence to inform recommendations.			
	50. Link between each recommendation and key evidence (text description and/or reference list).			
	51. Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline.			
External Review	52. Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence).			
	53. Methods taken to undertake the external review (e.g., rating scale, open-ended questions).			
	54. Description of the external reviewers (e.g., number, type of reviewers, affiliations).			
	55. Outcomes/information gathered from the external review (e.g., summary of key findings).			
	56. How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations).			
Updating Procedure	57. A statement that the guideline will be updated.			
	58. Explicit time interval or explicit criteria to guide decisions about when an update will occur.			
	59. Methodology for the updating procedure.			

Specific & Unambiguous Recommendations	60. A statement of the recommended action Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects).			
	61. Relevant population (e.g., patients, public).			
	62. Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply).			
	63. If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline.			
Management Options	64. Description of management options.			
	65. Population or clinical situation most appropriate to each option.			
Identifiable Key Recommendations	66. Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms.			
	67. Specific recommendations grouped together in one section.			
Facilitators & Barriers To Application	68. Types of facilitators and barriers that were considered.			
	69. Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation).			
	70. Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography)			
	71. How the information influenced the guideline development process and/or formation of the recommendations.			

Implementati on Advice/ Tools	72. Additional materials to support the implementation of the guideline in practice.	Green	Green	Green
Resource Implications	73. Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs).	Green	Red	Green
	74. Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.).	Green	Green	Green
	75. Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course).	Green	Green	Green
	76. How the information gathered was used to inform the guideline development process and/or formation of the recommendations.	Green	Green	Red
Monitoring/ Auditing Criteria	77. Criteria to assess guideline implementation or adherence to recommendations.	Green	Green	Red
	78. Criteria for assessing impact of implementing the recommendations.	Red	Green	Green
	79. Advice on the frequency and interval of measurement	Red	Green	Green
	80. Operational definitions of how the criteria should be measured.	Red	Green	Green
Funding Body	81. The name of the funding body or source of funding (or explicit statement of no funding).	Red	Green	Red
	82. A statement that the funding body did not influence the content of the guideline.	Red	Green	Red
Competing Interests	83.Types of competing interests considered.	Green	Red	Red
	84. Methods by which potential competing interests were sought.	Green	Red	Red
	85. A description of the competing interests.	Green	Green	Red
	86. How the competing interests influenced the guideline process and development of recommendations.	Green	Red	Red
Green = Present; Red = Absent.				

Appendix H

Summary Table of Pertinent Results from Nine RCTS Including Pain Outcome Measures

Author	Study Size	Chronicity	Age Groups	OTC Pain OM	SMT Pain OM	Difference
Hancock et al ⁽¹²⁾	60 participants OTCIG	ALBP	μ 39.5 OTCIG	NSAIDS μ 6.4 using NPRS	HVLA-SMT μ 6.7 using NPRS	Δ 0.3
	60 participants SMTIG		μ 41.4 SMTIG			
Heymann et al ⁽¹⁸⁾	38 participants OTCIG	ALBP	μ 37.51 OTCIG	NSAIDS μ 14.42 using RMQ	HVLA-SMT μ 13.46 using RMQ	Δ 0.96
	37 participants SMTIG		μ 34.14 SMTIG			
Hurwitz et al ⁽²¹⁾	170 participants OTCIG	ALBP	μ 49.4 OTCIG	NSAIDS & MRS. μ 10.5 using RMQ	HVLA-SMT μ 10.3 using RMQ	Δ 0.2
	169 participants SMTIG		μ 51 SMTIG			
Juni et al ⁽¹¹⁾	52 participants OTCIG	ALBP	μ 36.5 OTCIG	NSAIDS μ 6.3 using BS-11	HVLA-SMT μ 6.8 using BS-11	Δ 0.5
	52 participants SMTIG		μ 34.3 SMTIG			
Goldstein et al ⁽¹⁷⁾	46 participants ALBP OTCIG	ALBP	μ 51.8 OTCIG	NSAIDS & MRS. μ 10.5 using RMQ.	HVLA-SMT μ 10.3 using RMQ.	Δ 0.2
	41 participants SALBP OTCIG	SALBP	μ 51.8 SMTIG			
	83 participants CLBP OTCIG	CLBP				
	37 participants ALBP SMTIG					
	55 participants SALBP SMTIG					
	77 participants CLBP SMTIG					
Hondras et al ⁽²⁰⁾	49 participants OTCIG	SALBP	μ 63 OTCIG	Unspecified OTCIG μ 1.6 using RMQ.	HVLA-SMT μ 2.7 using RMQ	Δ 1.1
	96 participants SMTIG	CLBP	μ 63.8 SMTIG			
Schneider et al ⁽¹³⁾	35 participants OTCIG	SALBP	μ 41.3 OTCIG	NSAIDS μ 5.7 using NPRS	HVLA-SMT μ 5.5 using NPRS	Δ 0.2
	52 participants SMTIG		μ 41.4 SMTIG			
Hoiriis et al ⁽¹⁹⁾	50 participants OTCIG	SALBP	μ 40.5 OTCIG	MRS μ 3.95 using VAS	HVLA-SMT μ 4.52 using VAS	Δ 0.57
	48 participants SMTIG		μ 42.2 SMTIG			
Giles et al ⁽¹⁶⁾	40 participants OTCIG	CLBP	μ 41.8 OTCIG	NSAIDS μ 5 using VAS	HVLA-SMT μ 3 using VAS	Δ 2
	35 participants SMTIG		μ 50 SMTIG			

Abbreviations: Outcome measure (OM), Royland Morris questionnaire (RMQ), numerical pain rating scale (NPRS), visual analogue scale (VAS), 11-point box scale (BS-11), non-steroidal anti-inflammatory drugs (NSAIDS), muscle relaxants (MRS), mean average (μ), acute low back pain (ALBP), subacute low back pain (SALBP), over the counter intervention group (OTCIG), spinal manipulation therapy intervention group (SMTIG), high velocity low amplitude spinal manipulation (HVLA-SMT), average (μ), difference (Δ).

Appendix I

Summary Table of Pertinent Results from Three Published Literatures Including Pain Outcome Measures

Author	Study Size	Chronicity	Age Groups	OTC Pain OM	SMT Pain OM	Difference
Prinsen et al ⁽²⁸⁾	208 participants OTCIG 576 participants SMTIG	CLBP	OTCIG & SMTIG μ 44.7	NSAIDS & MRS μ 2.76 using VAS	HVLA-SMT μ 2.87 using VAS.	Δ 0.11
Knauer et al ⁽³⁰⁾	727 participants OTCIG 588 participants SMTIG	CLBP	OTCIG & SMTIG Between 45-64	NSAIDS 0.9 using SF-12PCS	HVLA-SMT 1.0 using SF-12PCS	Δ 0.1
Goertz et al ⁽⁴⁾	375 participants OTCIG 375 participants SMTIG	Unspecified ALBP SLBP CLBP	OTCIG & SMTIG μ 30.9	NSAIDS + μ 3.5 using NRS	HVLA-SMT μ 2.6 using NRS	Δ 0.9

Abbreviations: Outcome measure (OM), numerical pain rating scale (NPRS), visual analogue scale (VAS), SF 12 physical component score (SF-12), non-steroidal anti-inflammatory drugs (NSAIDS), muscle relaxants (MRS), mean average (μ), acute low back pain (ALBP), subacute low back pain (SALBP), over the counter intervention group (OTCIG), spinal manipulation therapy intervention group (SMTIG), high velocity low amplitude spinal manipulation (HVLA-SMT), average (μ), difference (Δ).