ENOSI

Non-specific chronic lower back pain: A literary review between the relations of Non-specific chronic lower back pain and Osteopathy, along with manual therapy

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Abbreviations

1. **ANOVA,** Analysis of variance
2. **CLBP**, Chronic Lower Back Pain
3. **D.C**, Doctor of Chriopractic
4. **D.O**, Doctor of Osteopathy
5. **EMG**, Electromyogram
6. **ITT,** Intent-to treat
7. **MANOVA,** Multivariate analysis of variance
8. **MRI**, Magnetic Resonance Imiging
9. **NPR,** Numerical Pain Rating
10. **NSCLBP**, Non-Specific Chronic Lower Back Pain
11. **OA,** Outcomes assessment
12. **OMT**, Osteopathic Manipulative Therapy
13. **P.T**, Physical Therapist (American Physiotherapist)
14. **PPA,** Per protocol analysis
15. **RMDQ,** Roland Morris Disability Questionnaire
16. **SM**, Spinal Manipulation
17. **SMT**, Spinal Manipulitive Therapy
18. **TMS,** Transcranial magnetic stimulation
19. **UTST** Ultrasound Therapy
20. **UTS** Ultrasound

1. Introduction

Chronic lower back pain affects approximately 632 million people world wide and is the leading cause of disability (Licciardone, Gatchel et Aryal, 2016). Statistically it tends to affect woman more then men and people in middle age. Woman make up 64% of the chronic lower back pain population and the median age is 41 (Licciardone et al., 2016). Over 50% of People with chronic lower back pain have other pre-existing conditions such as; hypertension; diabetes; depression; osteoarthritis; previous back injuries or surgeries (Licciardone et al., 2016). It was also found that high percentages of people with CLBP had depression and anxiety/distress, which often osteopathic lesions were found (Licciardone, Gatchel, Kearns et Minotti, 2012).

Non-specific chronic low back pain (NSCLBP) is classified as having back pain for more than 3 months, without any presence pre-existing pathologies serious psychiatric conditions; scoliosis; pathologies that can cause systemic or local inflammation as well as no previous injuries or surgery or drug/alcohol abuse and no current pregnancy (Andersson et al., 1999). The consequences are an excess or deficit in spinal stability, which underlies their pain disorder. A potential to impact on both the physical and cognitive drivers of pain leading to resolution of the disorder. This places a tremendous cost and burden on society (O'Sullivan, 2005).

There are many factors that can cause NSCLBP. Decreases in size and thickness of the multifidus muscle at rest and during a contraction and asymmetry of left and right is consistent in people with NSCLBP via M.R.I, C.T and ultrasounds imaging. Compared to a group of healthy controls who did not show asymmetry during imaging (Wallwork, Stanton, Freke et Hides, 2009).

Associations with an adaptive (protective) motor response associated with a functional reduction of the lumbar lordosis with associated lumbar multifidus inhibition, to unload sensitized neural tissue. A mal-adaptive motor response, represented by a functional increase in lumbar lordosis with associated back muscle guarding, resulting in further neural compromise and direct aggravation of the disorder. Normalising the motor control impairments (to functionally reduce the lumbar lordosis) would be indicated and effective (Elvey and O'Sullivan, 2004).

Most of the scientific Osteopathic literature/research on NCSLBP is done with muscular and articular techniques. Very few studies have been published using techniques such as cranial; visceral or facial treatments on people with NSCLBP. There a far fewer academic articles in osteopathy compered other manual therapists who use the same techniques to treat NSCLBP. Many studies from chiropractors and physiotherapists using articular; muscle energy and myofascial release have been shown to have high results when treat people with NSCLBP (Bronfort, Haas, Evans, Leininger et Triano, 2010).

In osteopathy our approach when treating an individual, we are guided by principles, relating to the patient. We view the patient as a whole functioning unit, taking into account all systems of physiology and anatomy.

The body is a self-regulating, functional unit in which function and structure are inter-related, and healthy tissues require proper circulation of all body fluids. Skilled palpation and a detailed knowledge of anatomy, physiology and biomechanics guide the osteopath to assess and restore balance within and between all the systems of the body; musculoskeletal, cardiovascular, neurological, cranial and visceral. In health, the body seeks to maintain a balance within and between these systems.

The osteopath uses a wide array of manual approaches to reduce and resolve strains, stress and dysfunction in all areas of the body. The goal is to remove restrictions to vascular, neural and biomechanical mechanisms and ultimately support the natural healing mechanism by promoting autoregulation (Canadian Federation of Osteopaths., 2013).

An osteopath would approach NSCLBP by analysing any disfunctions of the low back as well as searching for other disfunctions through out the body that can possibly be the root cause of the issue or increase the intensity of the low back problem.

Osteopathy was introduced as a science, philosophy and practice by Andrew Taylor Still, MD in the 1870's. Disheartened with his tools during a deadly meningitis outbreak, Still began developing a manual, patient centered approach.

Many osteopaths since Still have contributed their life's work to Osteopathy – as a science and a practice. There are two streams of osteopathy recognized internationally, a medical stream of Osteopathic Physicians and Surgeons, and a manual stream of Osteopaths.

Canada represents a unique situation as it is one of a few countries' worldwide in which both streams of osteopathy are represented within the different provinces. Currently, the medical stream of Osteopathic Physicians and Surgeons falls under the legislation and licensure of the individual provincial Colleges of Physicians and Surgeons. Individual associations represent Osteopaths provincially. The Canadian Federation of Osteopaths (CFO) in turn, represents these provincial associations nationally. The CFO maintains membership in the international body, the Osteopathic International Alliance (OIA). The purpose of the OIA is to advance the practice of manual osteopathy and osteopathic medicine throughout the world (Canadian Federation of Osteopaths., 2013).

What differs Quebec osteopaths from osteopathic physicians and surgeon's is that we only used manual therapy to treat our patients. Osteopathic physicians may use other methods to treat patients such as prescriptions sometimes also using manual therapy.

The physiotherapy philosophy also views the body as a whole and will use treatment plans to target the problem area as well as anything elsewhere on the on the body that may be the root cause or maintain the issue. The physiotherapist will often recommend exercises that to balance muscle tone. This ensures that the muscle causing the pain is strong and stable, it will able to function properly and cause less pain compared to when it is weak and retracted.

Physiotherapists often treat NSCLBP, they have a different approach compared to osteopathy. Physiotherapists use a combination of manual therapy; electrostimulation; rehabilitation exercises and stretches; hot and cold therapy as well as dry needling. They will also prescribe or fabricate an application of assistive, adaptive, supportive and protective devices and equipment (Canadian Physiotherapy Association., 2019). They will target weak muscles that can influence the low back to have poor muscle tone which may cause pain and poor posture. This is done by recommending a series of exercises which specifically target inhibited muscles. Inhibited postural muscles like the transvers abdominus may accentuate lumbar lordosis and cause multifidi's and other back muscles to retract by shortening their length. When a muscle is overstretched it is at its weakest length to perform a contraction thus inhibiting the muscle. A hyper lordosis according to a physiotherapist may be the root cause of back pain as it over starches abdominal muscle, inhibiting their function while shortening back muscle which can decrease mobility; compress and use the vertebras\discs unevenly (Lakeview, 2019).

The medical approach to NSCLBP is often comprised of using either a combination of different treatments or trying one at a time to see what works best. Medical doctors will often prescribe anti-inflammatories or pain killers to treat the pain if it is too debilitating. Sometimes a few medications will be combined to have a stronger effect such as anti-inflammatory and pain killer with a muscle relaxant. A medical back or pain specialist will educate the patient on way to limit pain. If it is ineffective the next step is usually cortisone injections in the painful areas. Other times if the pain is not too incapacitating, they will refer the patient to a manual therapist and other professional the help to treat pain, while sometimes also receiving medication. In other cases, certain drugs such as anti-neuropathy (Lyrica) are used. Depressive disorders may cause chronic pain and muscle stiffness, which doctors use anti-depressants to treat. Hormone or neurotransmitter imbalance can influence muscle tone and the patient's perception of pain. If all previous treatments are ineffective, narcotics might be prescribed (Francis H. Shen, Dino Samartzis et Gunnar B.J. Andersson, 2006).

For CLBP, depending on what the cause is, surgery may be used to relive pain. For a herniated disc, there will be a laminectomy of the disc and a fusion of the 2 vertebrae that the disc was between. For foraminal stenosis and radiculopathy caused by osteophytes, the osteophytes will be surgically removed along with tumours a cysts that may cause radiculopathies (Cohen, Argoff et Carragee, 2008).

In acupuncture, pain and stiffness are treated placing a needle just under the skin along certain lines of energy called meridians. The needle is place on a point of a meridian that is blocking the flow of energy to the affected zone. In acupuncture it is believed that the energy of the liver, governs the muscle; tendons; articulations and ligaments. Certain sensitive points on the low back may correspond to a meridian linked to an organ which is block in energy. The acupuncturist may place needles on low back painful points that correspond to a certain organ("The Chinese Medicine Meridian System," 2018).

Other people believe that acupuncture is nothing more than the placebo effect, according to the metanalysis done by Ernst and White, "there is not enough evidence to suggest the acupuncture results were superior to that of the placebo effect (Ernst et White, 1998)"

This literary review will be focused on finding the most effective method and techniques for an osteopath, to be able to successfully treat non-specific chronic lower back pain. The analyzed articles will give us a very clear idea on what methods works best to treat this

condition. I have chosen several articles with double blind and placebo groups which. Some articles use scan imaging and EMG of lower back, which can help avoid bias.

2. Methodology

2.1. Research type

The research project style is a literature review. The latter makes it possible to group together a set of studies related to the same subject for inventory and critical analysis (Fortin, 2006). The goal of this literature review is to answer the following question: What are the osteopathic interventions used to treat non-specific chronic lower back, in people with no underlying pathologies from ages 18 and older, using osteoarticular and muscular techniques.

2.2. Procedure

Data bases

The research of the articles was done with Google scholar, PubMed, EM premium.

Keywords

Several keywords were used that were linked to osteopathy and non-specific chronic lower back pain and the technics used to treat this condition. For the research, the different themes of the keywords were associated with the words *AND* or *OR* in the databases.

Data bases: Google scholar, PubMed and EM premium		
Keywords link with osteopathy	**Keywords link with non-specific chronic lower back pain**	**Keywords link with the techniques used to treat this condition**
O.M.T	NSCLBP	Thrust
Osteopathic manipulative therapy	CLBP	Strain counter strain
Manual therapy	Low back pain	Muscle energy
	Non-specific chronic lower back pain	mobilizations
	Chronic low back pain	High velocity low amplitude
	Lumbago	General osteopathic treatment

Figure 1 Keywords

Selection criteria

Inclusion criteria:

- People who are 18 years of age and over.
- Articles from the year 1970 and newer.
- Full text.
- Texts in English only.
- Articles written by health practitioners talking about non-specific chronic lower back pain and using similar techniques to osteopathy, such as chiropractors and physiotherapists as well as M. D's.
- Articles discussing muscular and articular techniques to treat non-specific chronic lower back pain or a specific techniques ability to treat NSCLBP.
- Studies using randomization and/or single blind and/or double blind and/or placebo group or comparison of healthy individual vs individuals with non-specific chronic lower back pain.
- Articles containing standardized pain and disability questionnaires.

Exclusion criteria:

- Articles in languages other than English.
- Subjects under 18 years old.
- No access to full article.
- Article discussing different techniques than muscular and articular. Ex: Visceral techniques.
- Articles older than 1970.
- Articles that do not speak about treatment plans or technique efficiency for non-specific chronic lower back pain.
- Articles that only use palpatory tests
- Articles without standardized pain and disability questionnaires

2.3. Study selection

At the beginning n=585 articles were selected. Using the manual research technique with google scholar, suppression of repeating articles and articles that had nothing to do with my subject was done by reading titles and abstracts (n=527; 527/585) articles were rejected. Out of the (n=58; 58/585) sources that were retained, (n=18; 18/585) of them were rejected by

title and abstract as they did not match my inclusion criteria. The complete text of (n=40; 40/585) articles were analysed, (n=24; 24/585) articles were rejected. (n=17; 17/585) of the articles were not specific enough and did not respect inclusion criteria. (n=7; 7/585) or the articles were literary reviews. (n=16; 16/585) sources were kept, upon re-analysing them (n=3; 3/585) of the sources lacked too much information on my subject. (n=13; 13/585) sources were kept for the final analyses.

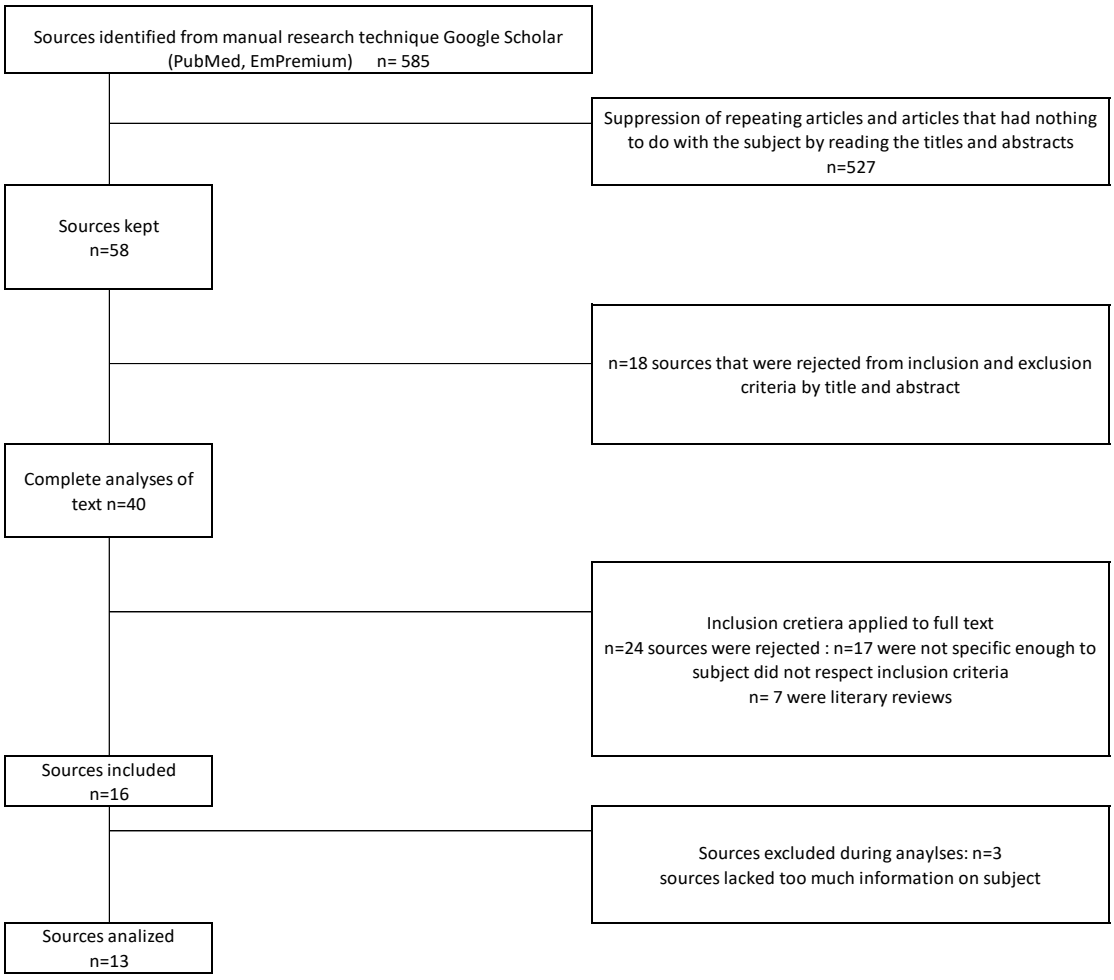

Figure 2 Flux diagram: Inclusion and exclusion process of sources

2.4. Charting the data

After reading the full article from the ones I have selected, I will create an excel spread sheet to classify the data collected which pertinent and answer my research question.

- The characteristics of the references included: title of article; names of authors, year of publication; country of study, Publisher name.
- Research type: type of study (quantitative, qualitative, trial etc.), goals of the study, characteristics of participants (number, age, sex)
- Data linked with osteopathic interventions used to treat non-specific chronic lower back pain: types of techniques used, health professional involved, test statistic used.
- Results, limits and analyse of study.

2.5. Data analysis

A descriptive analysis will be used to represent the data, to compare the different information collected and to critique each article about; limiting factors, strong points and common links they share.

3. Results

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
(Clark et al., 2018)	USA	Contempo rary Clinical Trials.	Randomized, single blinded sham-controlled trial.	To observe the effects the physiological effects of spinal manipulation therapy on subjects who had NSCLBP.	162 Participants which were split up into three groups of 54. The age of the participants was between 18 to 45.	D.C, D.O, P.T	S.M.T, mobilizations and sham laser therapies twice a week for three weeks.	MRI, T2, EMG; TMS to scan the low back for changes from treatments. Disability questionnai res and surveys used were OA; NPR; RMDQ; ANOVA; ITT; MANOVA	Treatments that used a combination of S.M.T and mobilizations had a significant reduction of T2 asymmetry compared to the sham placebo treatments for both short and long term.	Missing data caused by participant reported or investigator observed, related to treatment effectiveness. Missing data due to equipment failure. The study used various strategies to balance the results from	21.75

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								; PPA which monitored data along the study.		The missing data. Estimation was used to help balance the missing observations for the ITT analysis. A sensitivity analysis was done to determine if the missing data was random loss.	
(Licciardone, Kearns, Hodge et Bergamini, 2012)	USA	JAOA	Randomized double-blind sham-controlled 12 week trial.	To measure the baseline concentrations of interleukin, and tumor	70 Participants from ages 21 to 69. 40 female 30	D.O	High-velocity, low amplitude thrusts; moderate-velocity,	10-cm visual analog scale, the Roland-	Participant who had “key osteopathic lesions” had greater levels	The possibility of type I errors in the some of the findings due to	20.5

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				necrosis factor in patients with NSCLBP and the correlations of number of "key osteopathic lesions" as well as the changes in cytokine concentrations with OMT.	male, 38 OMT 32 sham OMT		Moderate-amplitude thrusts; soft-tissue stretching and pressure; myofascial stretching and release; strain counter strain and muscle energy. These techniques were used mostly at the lumbosacral, iliac, and pubic regions. The sham OMT delivered with the same	Morris Disability Questionnaire, and the Medical Outcomes Study Short Form-36 Health Survey. Baseline cytokine measures were performed using blood samples. The musculosk	cytokines and interleukins in blood. Those who received OMT had significantly greater TNF-α concentration reductions compared with those who received sham OMT, however there were no significant changes in interlukin concentrations.	analyses of 5 different cytokines and 4 clinical measures. Type II errors may also have occurred because of only 15% of participants had pre-treatments cytokine measures and 12% had matched post treatments measures. Due to small sample size it	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
							constraints and was used in the same regions as active OMT. Sham OMT involved hand contact, active and passive range of motion, with light touch, improper patient positioning, purposely misdirected movements, and diminished provider force.	eletal table of the Outpatient Osteopathi c SOAP Note Form20 and TART was used to determine dysfunctio ns in the thoracic Osteopathi c dysfunctio ns.		is possible that important associations might have been missed. Cytokine concentrations may have been varied by thing such as medication use which was not tightly controlled during the study. They believe that the randomization process might have mixed up	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
										potential confounders by allocating them comparably between the OMT and sham OMT groups. The matching of patient pre- and posttreatment cytokine measures further diminished the potential for confounding bias.	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
(Licciardone, Kearns et Crow, 2014)	USA	Manual Therapy	A randomized, double-blind, sham-controlled, 2 x 2 factorial design	To determine the biomechanical dysfunction changes in low back pain reduction with OMT.	230 participants over 12 weeks	DO's with factulty, fellow and resident physicians.	High-velocity, lowamplitude thrusts; moderate-velocity, moderate amplitude thrusts; soft tissue stretching, myofascial stretching and release; strain counter strain and muscle energy.	IQR ¼; VAS; The Roland-Morris Disability Questionnaire and The SF-36 general health scale.	Significant improvements in each biomechanical dysfunction were observed with OMT; however, only psoas syndrome remission occurred more frequently in people with NSCLBP. Remission of psoas syndrome was the only change in.These	Lack of data of biomechanical dysfunctions, from 225 participants who received sham OMT, which were consequently excluded. Data had to be imputed on biomechanical dysfunction in 5% and 23% of patients at baseline and week 8. There's a possibility that subgroup	24

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
									findings suggest that remission of psoas syndrome may play a key role in explaining improvement in patients with chronic NSCLBP and OMT.	comparisons of NSCLBP responders and non-responders may have been biased by unknown confounders that were no longer randomly distributed within subgroups. NSCLBP responders were more likely than non-responders to	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
										have completed college education. This was an uncontrollable factor in the multivariate analysis.	
(Cleland et al., 2009)	USA	Spine	Randomized clinical trial	To examine the effects of three different manual therapy techniques in a patient population with NSCLBP.	112 patients, ages between 18 to 60, 49% female. Participants were split up into 3 groups, each group only recived one of the techniques.	P.T	Supine SMT thrusts, range of motion, Side-Lying Thrust and non-thrust manipulation technique (low-velocity, high amplitude oscillatory force).	Oswestry Disability Questionnaire and the Numerical Pain Rating Scale at baseline.	There was no significant difference between the 2 thrust groups however the was a significant difference between non-thrust and thrust group	Inability to track the number of patients screened for eligibility in the study from each of the settings. The study did not include a control group.	24.5

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
									even up untill 6 months. Thrust therapy had greater effects the non-thrust which was hypothisized by the neurophysiological response it produced.	They couldn't determine if the use of thrusts for patients who are positive on the Clinical Prediction Rule, would produce superior outcomes when compared to no treatment. Spontaneous recovery within the first few days or weeks is believed to	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
										happen often with an acute episode of LBP, however most patients in this trial had symptoms for a much longer time which made spontaneous resolution unlikely. There was no difference in symptom duration among the treatment groups, therefore	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
										spontaneous resolution would not explain the different recovery rates between groups.	
(Senna et Machaly, 2011)	Egypt	Spine	Rondomized trial	To assess the effectiveness of spinal manipulation therapy for NSCLBP and to determine the effectiveness of SMT for long-term pain and disability for NSCLBP	60 participants ages between 20 to 60. 12 sessions of manipulation or sham manipulation , followed by back exercise in form of pelvic tilt	M.D's with over 10 years experi ence for low back pain.	S.M.T	Subjective Patient-Based Assessmen ts, Pain levels were assessed on a visual analog scale.	Groups Experienced significantly lower pain and disability scores compared with control group after 1-month period. By the end of the10-month period,	This trial had limitations caused by missing data when certain patients refused a follow ups a certain intervals. Multiple imputation was used to	22.5

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				after initial treatment	range of motion. The first recived a sham SMT using minimal force over a 1-month period (control group), and no treatments for the subsequent 9 months. The second group recived the real SMT three times weekly over				patients with maintained SMT had significantly lower pain and disability scores compared with the patients of the nonmaintaine d SMT group.	compensate the missing data.	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					a 1-month period, with no treatments for the subsequent 9 months. The third group also received the real SMT as second group over a 1-month period "initial intensive SMT," along with "maintenanc e SMT" every 2						

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					weeks for the next 9 months (maintained SMT group). Techniques were defined as high velocity low amplitude thrusts.						
(Haas, Vavrek, Peterson, Polissar et Neradilek, 2014)	USA	Spine	A randomized controlled trial	To identify the dose-response relationship between visits to a chiropractor for spinal manipulation and NSCLBP outcomes and	400 participants split into 4 groups of 100 received a quantity of 0, 6, 12, or 18 SMT sessions from a	D.C	S.M.T and light massage	Self-reported modified Von Korff pain and disability scales validated by Underwoo	The number of spinal manipulation visits had modest effects on NSCLBP compared to those of 18 hands-on visits to a	Nine participants were completely lost to follow-up. No sham group however they justified it by saying “it would be	24.5

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				to determine the efficacy of manipulation by comparison with a light massage control.	chiropractor. All participants were given 18 treatment, 3 per week for 6 weeks. The control group received the sham SMT which consisted of a light massage, the other group received the real SMT. The sham treatment was that of a			d et al.; pain unpleasant ness; Physical and Mental Component Summary Scales of the short-form; Health State Visual Analog Scale from EuroQol and Fear-Avoidance Beliefs	chiropractor. 12 visits yielded the most favorable results but was not well distinguished from other dose levels.	impossible to blind participants because half received visits for both treatment and control and could compare interventions."	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					therapeutic massage however lighter pressure was used and shorter duration times.			Questionnaire.			
(Bicalho, Setti, Macagnan, Cano et Manffra, 2010)	Brazil	Manual Therapy	A randomized controlled trial	To analyse the immediate effects of high-velocity spine manipulation on paraspinal activity during trunk flexion/extension.	40 participants were randomized into 2 groups, the control and the SMT group. Control group had 8 males and 12	One D.O with 5 years experience.	High-velocity spine manipulation	Oswestry low back pain and Visual analogue scale were used to asses back pain and disability. An EMG was used to	The SMT group had significantly less pain intesnsity compared to controls. Using the EMG, the flexion phase values did not change	This study does not speak about limitations.	17

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					females. The SMT group had 5 Males and 15 females. The SMT group received a high-velocity lumbar manipulation on L4-L5. The control group remained in this position without any other intervention. Reevaluation was done in both groups			moniter paraspinal muscle activity.	significantly following manipulation for any group. There was a significant decrease in the relaxation and extension phase values for the manipulation group but not for the control group. The results suggest that a highvelocity SMT is able to acutely reduce		

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					immediately after the intervention.				abnormal EMG activity during the full-flexion static phase and activation during the extension phase.		
(de Oliveira, Liebano, Costa, Rissato et Costa, 2013)	Brazil	Research Report	A randomized controlled trial. The trial used a 2-arm, prospectively registered, randomized controlled trial with a blinded assessor.	To analyze the immediate effects of a single, region-specific SMT versus a single non–region-specific spinal manipulation which was applied on an upper thoracic	148 participants with 74 in each group. Only one high-velocity manipulation was done to the upper thoracic region of the participants	P.T with 4.5 years of experience with low back pain.	S.M.T	Numeric Pain Rating Scale; Roland Morris Disablilty Questionnaire; Pressure Algometer at the	Both groups experianced an immediate decrease of pain intensity; however no differences were observed between the 2 groups. The immediate changes in	Patients and therapists were not blinded. Lack of mixed population in trial participants.	22

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				vertebra in patients NSCLBP.	in the non–region-specific manipulation group as well as to the lumbar areas of the region-specific manipulation group.			levels of L3 and L5 bilaterally as well as on the muscle belly of tibalis anterior also bilaterally.	pain intensity and pressure pain threshold after a single high-velocity manipulation do not differ by region-specific versus non–region-specific manipulation techniques in patients NSCLBP.		
(Clark et al., 2011)	USA	BMC Musculos -keletal Disorders	A case control study	To determine is a single SM alter corticospinal excitability of	10 participants with NSCLBP and 10	D.C and D.O.	Transcrainial magnetic stimulation was used quantify motor evoked	Questionna ires used in this study were Visual	SM did not alter the erector spinae MEP amplitude in	Each subject only received one single spinal manipulation	NA

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				the erector spinae muscles in patients with NSCLBP or in asymptomatic controls. Secondly does a single SM alter the excitability of the Ia reflex pathway of the erector spinae muscles in patients with NSCLBP or in asymptomatic controls. Thirdly do the changes in corticospinal	healthy controls. Each group had 5 men and 5 women. During the SM the treating physician and at least one other researcher listened very crefully during the SM procedure, to note down participants who		potential amplitude as an index of corticospinal excitability, and electromechanical tapping of the lumbar paraspinal muscles to quantify short-latency stretch reflex amplitude as an index of Ia reflex pathway excitability. A single high-velocity low-amplitude thrust was	analogue scale; Roland Morris Disability Questionnaire; Tampa Scale for Kinesiophobia. An EMG was used to mesure mesure excitability.	patients with NSCLBP or in asymptomatic controls. SM did not alter the erector spinae stretch reflex amplitude in patients with NSCLBP or in asymptomatic controls.Study participants exhibiting an audible response exhibited a 20% decrease	to test the neurological effects, they claim that the effect would have been more pronounced if the subjects had received a series of treatments. They were not able to rule out placebo effect from patients who received and audible pop.	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				or Ia reflex pathway excitability vary depending on whether an audible response occurs during SM.	exhibited an audible "pop". The subject was unaware that the "pop" was being documented.		delivered to the lumbar spine, 10-minutes later the neurophysiolog ic testing session was repeated.		in the stretch reflex.		
(Goss Jr et al., 2012)	USA	Journal of Electromy ography and Kinesiolo gy	An experimental study	To determine if non-thrust manual therapy could have an effect on asymmetry of left and right erector spinae muscles and stretch reflex amplitude in	Out of the 9 patients 5 were women and 4 were men. The study was based on the concept of "when a muscle is rapidly stretched, a	D.O, P.T	S.M.T, the non-thrust techniques used were muscle energy, myofascial release, and strain-counterstrain.	EMG, Visual Analogue Scale, palpatory tests were also used by the practitioner s to asses tenderness and	Following the MT intervention the stretch reflex asymmetry was reduced.	This study was limited by the lack of a control group and small sample size.	NA

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				nine patients NSCLBP.	short-latency stretch reflex is elicited due to the excitation of the receptive endings of the Ia afferent fibers within the muscle spindles (Schuurmans et al., 2009)". receptive endings of the Ia afferent fibers within the muscle			somatic dysfunctio ns.			

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					spindles (Schuurmans et al., 2009)". An EMG was used to mesure erector spinae muscle stretch reflex responsivene ss activity of the muscle in response to mechanical tapping. During the stretch reflex testing, study participants						

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					were asked to sit with an upright posture while their hands rested in their lap. They were seated in a swivel-base chair with the thigh at 90-degrees relative to the trunk, the lower leg at 45 degrees relative to the thigh, and the lumbar spine						

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
					in a neutral posture.						
(Licciardone, Minotti, Gatchel, Kearns et Singh, 2013)	USA	Ann Fam Med	A randomized double blind sham controlled tiral	To determine the efficiancy of osteopathic manual treatment and ultrasound therapy for NSCLBP.	455 patients were randomized to OMT aged 21 to 69 years, six treatment sessions were provided over 8 weeks.	15 D.O's.	The lumbosacral, iliac, and pubic regions were targeted using high-velocity, low-amplitude thrusts; moderatevelocity, moderate-amplitude thrusts; soft tissue stretching; myofascial stretch-ing and release; strain counter strain and muscle	Cochrane Back Review and Visual Analogue Scale was used to asses pain and disablity.	The OMT group had greater back pain improvments results compared to the sham OMT group. The UTS did not prove to be effeciant.	The limitations of our study. Comorbid conditions, work disability, and low back pain cotreatments were self-reported by patients, but were not verified through medical or employment records. Missing data had to be	25

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
							energy. Sham OMT was aimed at the same anatomical regions as active OMT. Sham OMT involved hand contact, active and passive range of motion, techniques that simulated OMT but that used such maneuvers as light touch, improper patient positioning,			imputed for 13% of patients at last treatment.	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
							purposely misdirected movements, and diminished physician force. The UST intervention was delivered after the OMT intervention, using the Sonicator 730, with a 10 cm2 applicator at an intensity of 1.2 W/cm2 and frequency of 1 MHz in continuous mode. Conductivity				

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
							gel was used to enhance absorptionand produce deep muscle thermal effects. About 150 to 200 cm2 of the lower back were treated. Sham UST was delivered in the same manner at a subtherapeutic intensity.				
(Castro-Sánchez et al., 2016)	Spain	Spine	A single blinded controlled	The goal of thr trial was to compare the effectiveness of spinal	Sixty-two patients with 62% females.	P.T's, 10 years experi ence	The techniqes consisted of side-lying pelvic girdle manipulation,	Roland-Morris Disability Questionna ire;	SMT showed greater reduction in disabilty compared to	Limitations were that only two clinicians performed the manipulative	25

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				manipulation VS functional techniques on pain, disability, kinesiophobia, and quality of life in patients with NSCLBP.		or more.	side-lying lumbar spine manipulation, Thoracic manipulation. The functional technique was a decompression for the sacrum from the iliacs with opned up boths S.I joints.	Oswestry Low Back Pain Disability Index; Numerical Pain Rate Scale; Tampa Scale of Kinesiopho bia; Short Form-36; McQuade test and forward spine flexion were used to asses	the functional technique. No differences were seen with pain; fear of movement and forward spine flexion. SMT therapy did not result in any clinically important short-term benefits over functional technique therapy.	therapy and functional technique intervention, which could limit the generalizabilit y of the results. Secondly data was only collected at a short-term follow-up of 1 month with a total of three sessions. No control group was included in the study, so it cannot be	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
								pain and disability.		determined if the improvements seen in both groups can be caused by interventions or the passage of time. They also stated that it would be useful to include in future trials a control or placebo group and collect data over a long-term	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
										follow-up period.	
(Bialosky, Bishop, Robinson, Zeppieri Jr et George, 2009)	USA	American Physical Therapy Associati on	A randomized controlled trial	To assess the immediate effects of SMT on thermal pain perception in people with NSCLBP and to determine whether the resulting hypoalgesia was a local effect and whether psychological influences were associated with	36 (10 men, 26 women). Quantitative sensory testing was used to assess temporal summation and A fiber–mediated pain perception. The participants were randomly assigned to ride a	P.T	S.M.T	Numeric rating scales; The Fear of Pain Questionna ire–III; The Tampa Scale of Kinesiopho bia; The Coping Strategies Questionna ire; The State-Trait Anxiety Inventory; The	Hypoalgesia to A fiber–mediated pain perception was not observed. Group-dependent hypoalgesia of temporal summation specific to the lumbar innervated region was observed. Pair-wise comparisons indicated	Limitations were that Only immediate effects of SMT were measured, so the authors are unable to comment on whether the inhibition of temporal summation is a lasting effect. The authors are also unable to comment on the relationship	23.5

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
				changes in pain perception	stationary bicycle, perform low back extension exercises or receive SMT. Sensory testing was reassessed to determine the immediate effects of each intervention on thermal pain sensitivity.			Anxiety Sensitivity Index were used to asses pain and disability	significant hypoalgesia in participants who received SMT, but not in those who rode a stationary bicycle or performed low back extension exercises. Psychological factors did not significantly correlate with changes in temporal summation in participants	between their findings and changes in clinical pain.	

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
									who received SMT. Inhibition of A fiber–mediated pain perception was similar for all groups. Inhibition of temporal summation was observed only in participants receiving SMT, suggesting a modulation of dorsal horn excitability which was		

Authors and year	Country	Publisher	Type of study	Goals of study	Participants and methodes	Health Profes - sionals	Techniques used	Test statistics used	Results	Limits	2010 Consort Checklist Score
									observed primarily in the lumbar innervated area.		

4. Discussion

A randomized control trial to determine the effectiveness and physiological effects of spinal manipulation and spinal mobilization compared to each other and a sham condition in patients with chronic low back pain: Study protocol for The RELIEF Study (Clark et al., 2018)

Limitation factors in this study was missing data caused by participant reported or investigator observed, related to treatment effectiveness. Missing data due to equipment failure. The study used various strategies to balance the results from the missing data. Estimation was used to help balance the missing observations for the ITT analysis. A sensitivity analysis was done to determine if the missing data was random loss. It was done with multivariate multiple imputation method under different scenarios. This study had many factors that lowered bias. The investigator, statisticians and data collectors were blinded. They were given identification codes only at the end of the study. The statisticians used R statistical language to block-randomize for the three experiments. The study had many standardized pain and disability forms for participants before and after treatments. MRI, T2 imaging, EMG and TMS were used to scan the low back for changes from treatments. This removes the subjective-ness and bias that a personal palpatory test and retest would provide. Having 2 different treatment groups and 1 sham group helped to reduce the placebo effect to make results more accurate. A large sample size increases accuracy of results and having D.O, D.C and P.T helps to have different viewpoints.

Associations of Cytokine Concentrations with Key Osteopathic Lesions and Clinical Outcomes in Patients with Nonspecific Chronic Low Back Pain: Results from the OSTEOPATHIC Trial (Licciardone, Kearns, Hodge et Bergamini, 2012)

Limitations of this study include the possibility of type I errors in the some of the findings due to analyses of 5 different cytokines and 4 clinical measures. Type II errors may also have occurred because of only 15% of participants had pre-treatments cytokine measures and 12% had matched post treatments measures. Due to small sample size it is possible that important associations might have been missed. Cytokine concentrations may have been varied by thing such as medication use which was not tightly controlled during the study. They believe that the randomization process might have mixed up potential confounders by allocating them

comparably between the OMT and sham OMT groups. The matching of patient pre- and posttreatment cytokine measures further diminished the potential for confounding bias. More research is needed to further understand the relationship between cytokine levels and people with NSCLBP, however the TNF-a showed good results. Strengths for this study includes the double blind, sham controlled 2x2 factorial design. Using cytokines to measure pain removes some subjectivity from the participants subjective perception of pain. Multiple standardized pain and disability questionnaires were used to gather information.

Changes in biomechanical dysfunction and low back pain reduction with osteopathic manual treatment: Results from the OSTEOPATHIC Trial (Licciardone, Kearns et Crow, 2014)

Strengths of this trial included double-blind, sham-controlled, 2x2 factorial design with allocation concealment, blinding of outcome assessors, high levels of treatment adherence and outcomes reporting, intention-to-treat analysis. It is possible that some degree of patient unblinding may have occurred. OMT was pragmatically assessed using a multimodal regimen to complement care and self-care for NSCLBP. Several techniques that were used in the trial, were validated for NSCLBP treatment by professional associations representing chiropractors and physiotherapists. The study was done over 12 weeks with a large sample size. D.O's and M.D's participated in the trial which may help to limit bias from the desired results of either health professional. The limitations of this study were a lack of data of biomechanical dysfunctions, from 225 participants who received sham OMT, which were consequently excluded. Data had to be imputed on biomechanical dysfunction in 5% and 23% of patients at baseline and week 8. There's a possibility that subgroup comparisons of NSCLBP responders and non-responders may have been biased by unknown confounders that were no longer randomly distributed within subgroups. NSCLBP responders were more likely than non-responders to have completed college education. This was an uncontrollable factor in the multivariate analysis. It's uncertain if other unknown and uncontrolled factors may have influenced the relationships between changes in biomechanical dysfunction with OMT and subsequent NSCLBP response.

Comparison of the Effectiveness of Three Manual Physical Therapy Techniques in a Subgroup of Patients With Low Back Pain Who Satisfy a Clinical Prediction Rule (Cleland et al., 2009)

Strengths of this study are the randomization process with sealed opaque envelopes with individually assigned index cards which placed participants in one of three groups. The examining therapist always remained blind to the patient's treatment group assignment. Patients were instructed not to discuss the types of manual therapy technique received with the examining therapist. Large sample size with 49% women and 51% men and the use of various standardized pain and disability questionnaires helps to eliminate some bias and subjective-ness. This study had follow-ups with the participants after the 1st and 4th week and lastly after 6 months. This helps us to understand short term and long-term effects of different techniques used. Comparing 3 different techniques helps us to understand which ones are more effective to treat NSCLBP. Major limitations of this study included the inability to track the number of patients screened for eligibility in the study from each of the settings. The study did not include a control group. They couldn't determine if the use of thrusts for patients who are positive on the Clinical Prediction Rule, would produce superior outcomes when compared to no treatment. Spontaneous recovery within the first few days or weeks is believed to happen often with an acute episode of LBP, however most patients in this trial had symptoms for a much longer time which made spontaneous resolution unlikely. There was no difference in symptom duration among the treatment groups, therefore spontaneous resolution would not explain the different recovery rates between groups. Placebo manipulation technique was not used, they were unable to determine the influence of placebo effects on the outcomes of the study. They believed the placebo effect would be equally represented in all group because of the use of a hand on standardized treatment schedule. Additional research is needed to further confirm the results of this study.

Does Maintained Spinal Manipulation Therapy for Chronic Nonspecific Low Back Pain Result in Better Long-Term Outcome? (Senna et Machaly, 2011)

The study was randomized using sequential-sealed envelopes prepared before arrival of the patients. Patients were randomized twice, first for the treating clinician and second for the treatment group. When the first envelope was opened only the treating clinician opened the sealed second envelope to record the allocation of patients as they started the trial. Patients who were manipulated by one physician were assessed throughout all the trial follow-up by the other

physician who was completely blind to group assignment of patients being assessed. Patients were prohibited to talk about the type of care they received. Having a “maintained” and a “non-maintained” manipulation group showed accuracy in in results for long- and short-term effects of SMT. Having as sham group helped eliminate placebo. Many standardized pain and disability questionnaires. A major limitation of this study was missing data from a few patients who refused a follow up appointment. Multiple imputation was used to compensate for missing data. Participants were followed for 10 months and had less pain and disability during. They are uncertain if the effects would last longer than 10 months however they believe that periodic visits from patients will help to prevent a future episode or the start of one.

Dose-response and efficacy of spinal manipulation for care of chronic low back pain: a randomized controlled trial (Haas, Vavrek, Peterson, Polissar et Neradilek, 2014)

Very large sample size. 4 groups of 100 participants one of them being a non-manipulation control group, were evaluated at 6, 12, 18, 24, 39, and 52 weeks. One hundred participants with NSCLBP were randomized to each of four dose levels of: 0, 6, 12, or 18 SMT sessions from a D.C. There was one violation of protocol where a patient accidentally received 13 SMT visits instead of 12. A major strong point of this study was the knowledge that 93% to 97% of participants in each treatment arm refrained from professional care outside the study and 94% to 95% abstained from prescription medication. This allows greater calculation of outside factors influencing results. Many standardized pain and disability questionnaires. Limiting factors were, nine participants were completely lost to follow-up. No sham group however they justified it by saying “it would be impossible to blind participants because half received visits for both treatment and control and could compare interventions.” They also wanted to avoid potential disappointment from participants, if they thought they may be receiving sham intervention.

Immediate effects of a high-velocity spine manipulation in paraspinal muscles activity of nonspecific chronic low-back pain subjects (Bicalho, Setti, Macagnan, Cano et Manffra, 2010)

This study uses an EMG to monitor paraspinal muscle activity before and after treatments. EMG was also performed during trunk flexion, extension and other movements to test paraspinal activity during active and static phases. Having a machine-based test and result, significantly lower bias and subjective-ness from the study, as comparted to having only

palpatory test and standardized pain and disability questionnaires. There was only one kind of manipulation of technique done on L4-L5 levels only. This process is great for showing accuracy of the single technique being studied. The assessor was blinded. The study had a control group. A small sample size was chosen based on minimal clinically important change. This justified that the sample size was numerous enough to detect changes. Compered to other trials this study only uses 2 standardized pain and disability questionnaires however the EMG results were able to reveal significant changes. This study does not speak about limitation which create a major weak point.

Immediate Effects of Region-Specific and Non–Region-Specific Spinal Manipulative Therapy in Patients With Chronic Low Back Pain: A Randomized Controlled Trial (de Oliveira, Liebano, Costa, Rissato et Costa, 2013)

Strong points of the study are, large sample size, blind assessor, algometer was used to measure pressure in lumbar region compared to a palpatory test alone it reduces bias. Assessor blinding was confirmed by asking the assessor to guess which area on the spine was manipulated, the assessor only guessed the correct location in 48.1% of the cases. 2 standardized questionnaires were used to measure pain and disability. Due to the goals of the study it was not possible to blind the participants or therapists. To ensure good randomization, the instructions on what zone to treat (thoracic or lumbar) was sealed in an envelop which was opened by the practitioner before the treatment. The randomization codes were placed in consecutively numbered, sealed, opaque envelopes to blind allocation of participants to groups. Therapists who took part in this study had at leased 4.5 years of experience with low back issues and manual therapy, they also specialized in SMT techniques. They argue that “it was not possible to blind the therapist or the patients due to the nature of the interventions, which does not eliminate the risk of bias. Blinding of therapists and patients is not feasible in trials with active treatment interventions, such as exercise or manipulation, or ethical (given requirements of an information sheet). Therefore, lack of blinding of the therapist or patients could be interpreted as a limitation of the study.” The feel that their study was limited by not having recruited participants from a mixed population. This study also lacked a placebo or non treatment group. They go on to state that the study had good results for its goal which was to asses affects of SMT for immediate short-term effects, therefore they are not sure if the results last more than 24 hours. They say “As neuroplastic changes take time to develop and the responses to spinal manipulation are different between patients with chronic and acute low

back pain, it is likely that studies recruiting patients with acute low back pain and with longer follow-up periods will provide different results."

Neurophysiologic effects of spinal manipulation in patients with chronic low back pain (Clark et al., 2011)

The use of EMG and electrodes to measure results objectively. Trial was done by 2 different health professionals, a D.C and a D.O. Healthy control group was included. Limitations of this trial include that fact each subject only received one single spinal manipulation to test the neurological effects, they claim that the effect would have been more pronounced if the subjects had received a series of treatments. They were not able to rule out placebo effect from patients who received and audible pop. They claim that it is unlikely their results were "driven by a placebo effect as one would likely expect to observe a concomitant change in corticospinal excitability– as a placebo effect would likely be assumed to have systemic effects (as opposed to having a local, selective effect on the stretch reflex only)."

Non-thrust manual therapy reduces erector spinae short-latency stretch reflex asymmetries in patients with chronic low back pain (Goss Jr et al., 2012)

EMG and electrodes used to measurer asymmetry in erector spinae muscles increases objectiveness and decreases bias. Non trust therapy included 3 different types of osteopathic techniques. Participants only received a single treatment session of non-thrust. The non-thrust MT treatment may have a more pronounced effect if it was repeated over a few weeks. Limiting factors, no control or sham group. Small sample size. They argue that having done only a single session non-thrust manual therapy with each patient might have influenced with the results, as it would be more effective if it were repeated a few times. They believed that the results might be variable amongst different age and population groups.

Osteopathic Manual Treatment and Ultrasound Therapy for Chronic Low Back Pain: A Randomized Controlled Trial (Licciardone, Minotti, Gatchel, Kearns et Singh, 2013)

Strong point of this study includes double-blind, sham-controlled, 2 × 2 factorial design. Randomization done by a computer program that generated pseudorandom numbers. Participants were then allocated to type of physician (faculty physician, predoctoral fellow, or resident) using stratified randomization. Instructions were given directly to the physicians using numbered, opaque sealed envelopes, which were placed in separate treatment files. Participants and outcome assessors remained unaware of group assignments at randomization. Treatments

were done at weeks 0, 1, 2, 4, 6, and 8 using 15 different physicians. The participants have the same physician at recurring treatments unless there was a scheduling conflict. Having 15 different physicians help to lower bias. Participants could also independently receive low back pain treatments, any co-treatments except OMT, other manual therapies, or UST, from any physician not associated with the study. Co-treatments were documented at 4-week intervals throughout the study. It may be possible that the co-treatments influenced the results. The OMT sessions had 10 different osteopathic techniques, which represent a typical well-rounded osteopathic treatment on the musculoskeletal system. The methods and techniques used for the sham group, had been used un previous studies which generated a robust placebo response when compared to other sham methods. Very large sample size. 2 standardized questionnaires were used to measure pain and disability. Limitations od this study includes work disability, and low back pain cotreatments were self-reported by patients but were not verified through medical or employment records. Missing data had to be imputed for 13% of patients at the final treatment. Sensitivity analyses and 2 other methods were also used to buffer missing data. The 2x2 factorial design of the study limited the ability to asses the different placebo effects from sham OMT and sham UTS groups.

Spinal Manipulative Therapy Has an Immediate Effect on Thermal Pain Sensitivity in People With Low Back Pain: A Randomized Controlled Trial (Bialosky, Bishop, Robinson, Zeppieri Jr et George, 2009)

Strong points. Single blinded, treating physiotherapist all had more than 10 years experience. Concealed allocation was done by a computer-generated randomized table of numbers created before the start of data collection by a researcher not involved in the recruitment or treatment of patients. Individual numbered index cards with the random assignment were folded and placed in sealed opaque envelopes. Another therapist who was blinded to baseline exam, opened the envelope and started treatments according to the group assignment. Outcome were assessed before baseline data, at 3-weeks and 1 month after the last treatment by an assessor blinded to the treatment allocation of the participants. The study used 3 different thrust technique and one functional technique to decompress sacrum from both iliac bones. The functional technique is the same one used in osteopathy. Limitations of study, only 2 therapists performed the SMT and functional technique which can limit the generalizability of results. They claim that results were limited because data was only collected 3 times for a month. They suggest a long-term study would have given better result as it was previously mentioned that 12 sessions along a 13-month period according to (Hass et al, 2014) gives

greater results. This study did not include non treatment control group which made it difficult to determine weather the improvements in back pain were due to treatments or the issue resolving itself over time.

Spinal Manipulative Therapy Has an Immediate Effect on Thermal Pain Sensitivity in People With Low Back Pain: A Randomized Controlled Trial (Bialosky et al., 2009)

Strengths of this study are the use of a machine to measure thermal pain, Medoc Neurosensory Analyzer (TSA 2001*). Compared to palpatory tests alone it can limit bias. Participants were blinded to the temperature being used from device. The participants were given a baseline temperature and a finishing temperature which was hotter. The finishing temperature had a pre-determined sequence to prevent an "order effect." They claim that to the best of there knowledge they were the first study which measured thermal pain sensitivity as an outcome for SMT with people experiencing NSCLBP. This made limited data available from previous sample size calculations, in previous studies. This is also why the sample size is small, they had set a minimum for 30 participants. Limitations include, and examiner that was not blinded to the type of intervention a participant received. Because of this they can not be certain of examiner bias influenced the results. They cannot be certain that the if their results were due to a direct effect mediated by the dorsal horn of the spinal cord, since previous studies of this nature were done on animals. They go on to state that "pain is a multifaceted sensation relying on the peripheral nervous system in combination with the spinal cord and supraspinal centers, and the effect of SMT on pain likely results from an interaction of sites across the nervous system. Spinal manipulative therapy has been suggested to influence pain through mechanisms related to the peripheral nervous system and the supraspinal centers. Although our findings of diminished temporal summation suggest a spinal cord mediated effect, other than assessing commonly reported psychological factors, we did not account for potential peripheral and supraspinal influences on our findings."

5. Strengths and limitations of project

Strengths

- Most of the arcticles selected are less then 10 years old
- Most articles had rigourus blinding and randomizaing methodes.
- Articles coming from different part of the world USA; Spain; Egypt ect which gives us a global idea on how Osteopathy and manual therapy is practised around the world.
- All articles used one and often several standardized pain and disability questionnaires.
- A few articles mesured improvments with machines such as MRI ect; wich can help to lower bias
- Certain articles had multiple different health practitoners such as P.T, D.C, and M.D which can contribute to a wider vision of NSCLBP.

Limitations

- I was forced to place a limit of articles from 1970 and newer because of the lack of research in osteopthy, I would not have had enough articles. It would have interesting to have done a study on all recent articles to give us a better idea of how it's practised today.
- I was also obliged to use articles with other health practitioners using same techniques as osteopaths, due to the lack of reaserche and articles availible.
- I did not haver accsess to most osteopathic jounral websites since it required a membership fee to view website and articles.
- I rejected many interesting articles with pertinant information on OMT and NSCLBP because they did not meet all my inclusion creiteria.
- Most of the scientifique rigourus trials and studies came from USA, it might not reflect how osteopathy is practised world wide since in the states they are considered physiciens. They have the ability to precribes and use medication and scans.

6. Conclusion

This literary review was done with the goal of fining, which osteopathic and manual therapy techniques (techniques that resemble OMT from other professions) yielded most favorable results for people experiencing NSCLBP. Sources were acquired using the manual research technique with google scholar. Out of 585 articles, 13 were retained for complete text analyses. The articles which were retained, used OMT and manual therapy to reduce and treat NSCLBP. 8 out of the 13 articles had results favouring OMT and manual therapy for NSCLBP. 8 articles had a reduction in pain and disability, increased mobility or decreased muscle asymmetry according to medical imaging. The other 5 articles spoke about partially achieving their goal or inconclusive results, and that further research would be necessary to advance the idea and increase favourable results result. Most of the articles had similar blinding techniques such as opaque envelops and computer generated. Most of the studies that were retained from the 13 articles were done in the USA. USA has an advanced field of osteopathy, the osteopathic physicians in the states have far less restrictions to medical equipment and research funding which is probably why they are able to produce more research then most of other countries. On average, out of the 13 articles the most favourable techniques to treat NSCLBP with OMT are SMT; strain-counterstain; muscle energy and joint mobilizations. The literature also suggests that repeated visits and maintenance visits have better results on NSCLBP than one single treatment. According most of the articles retained, OMT is effective to treat NSCLBP. This study may have gotten greater results if there was less restriction to osteopathic journals/articles which required membership fees. Having greater access to osteopathic research would have changed the criteria of exclusion, making it possible to only seek osteopathic articles, however having research from other professions may give us a different mind set on techniques at treatments plans that we perform.

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References

Andersson, G. B., Lucente, T., Davis, A. M., Kappler, R. E., Lipton, J. A. et Leurgans, S. (1999). A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. *New England Journal of Medicine, 341*(19), 1426-1431.

Bialosky, J. E., Bishop, M. D., Robinson, M. E., Zeppieri Jr, G. et George, S. Z. (2009). Spinal manipulative therapy has an immediate effect on thermal pain sensitivity in people with low back pain: a randomized controlled trial. *Physical therapy, 89*(12), 1292-1303.

Bicalho, E., Setti, J. A. P., Macagnan, J., Cano, J. L. R. et Manffra, E. F. (2010). Immediate effects of a high-velocity spine manipulation in paraspinal muscles activity of nonspecific chronic low-back pain subjects. *Manual therapy, 15*(5), 469-475.

Bronfort, G., Haas, M., Evans, R., Leininger, B. et Triano, J. (2010). Effectiveness of manual therapies: the UK evidence report. *Chiropractic & osteopathy, 18*(1), 3.

Canadian Federation of Osteopaths. (2013). What is osteopathy. Repéré à https://www.osteopathy.ca/what-is-osteopathy/

Canadian Physiotherapy Association. (2019). Physiotherapy in Canada. Repéré à https://physiotherapy.ca/physiotherapy-canada

The Chinese Medicine Meridian System. (2018). Repéré à https://kootenaycolumbiacollege.com/the-chinese-medicine-meridian-system/

Clark, B. C., Goss, D. A., Walkowski, S., Hoffman, R. L., Ross, A. et Thomas, J. S. (2011). Neurophysiologic effects of spinal manipulation in patients with chronic low back pain. *BMC musculoskeletal disorders, 12*(1), 170.

Clark, B. C., Russ, D. W., Nakazawa, M., France, C. R., Walkowski, S., Law, T. D., . . . Odenthal, J. (2018). A randomized control trial to determine the effectiveness and physiological effects of spinal manipulation and spinal mobilization compared to each other and a sham condition in patients with chronic low back pain: Study protocol for The RELIEF Study. *Contemporary clinical trials, 70*, 41-52.

Cleland, J. A., Fritz, J. M., Kulig, K., Davenport, T. E., Eberhart, S., Magel, J. et Childs, J. D. (2009). Comparison of the effectiveness of three manual physical therapy techniques in a subgroup of patients with low back pain who satisfy a clinical prediction rule: a randomized clinical trial. *Spine, 34*(25), 2720-2729.

Cohen, S. P., Argoff, C. E. et Carragee, E. J. (2008). Management of low back pain. *Bmj, 337*, a2718.

de Oliveira, R. F., Liebano, R. E., Costa, L. d. C. M., Rissato, L. L. et Costa, L. O. P. (2013). Immediate Effects of Region-Specific and Non–Region-Specific Spinal Manipulative

Therapy in Patients With Chronic Low Back Pain: A Randomized Controlled Trial. *Physical Therapy*, *93*(6), 748-756. doi: 10.2522/ptj.20120256

Ernst, E. et White, A. R. (1998). Acupuncture for Back Pain: A Meta-Analysis of Randomized Controlled Trials. *Archives of Internal Medicine*, *158*(20), 2235-2241. doi: 10.1001/archinte.158.20.2235

Fortin, F. (2006). *Fondements et étapes du processus de recherche*. Montréal: Montréal : Chenelière éducation.

Francis H. Shen, Dino Samartzis et Gunnar B.J. Andersson. (2006). Nonsurgical Management of

Acute and Chronic Low

Back Pain. *Journal of the American Academy of Orthopaedic Surgeons*.

Goss Jr, D. A., Thomas, J. S., Walkowski, S., Clark, S. C., Licciardone, J. C., Yue, G. H. et Clark, B. C. (2012). Non-thrust manual therapy reduces erector spinae short-latency stretch reflex asymmetries in patients with chronic low back pain. *Journal of Electromyography and Kinesiology*, *22*(5), 663-669.

Haas, M., Vavrek, D., Peterson, D., Polissar, N. et Neradilek, M. B. (2014). Dose-response and efficacy of spinal manipulation for care of chronic low back pain: a randomized controlled trial. *The Spine Journal*, *14*(7), 1106-1116.

Lakeview. (2019). Repéré à https://lakeviewphysio.ca/treating-chronic-lower-back-pain-with-physiotherapy/

Licciardone, J. C., Gatchel, R. J. et Aryal, S. (2016). Recovery From Chronic Low Back Pain After Osteopathic Manipulative Treatment: A Randomized Controlled Trial. *The Journal of the American Osteopathic Association*, *116*(3), 144-155. doi: 10.7556/jaoa.2016.031

Licciardone, J. C., Gatchel, R. J., Kearns, C. M. et Minotti, D. E. (2012). Depression, somatization, and somatic dysfunction in patients with nonspecific chronic low back pain: results from the OSTEOPATHIC Trial. *The Journal of the American Osteopathic Association*, *112*(12), 783-791.

Licciardone, J. C., Kearns, C. M. et Crow, W. T. (2014). Changes in biomechanical dysfunction and low back pain reduction with osteopathic manual treatment: Results from the OSTEOPATHIC Trial. *Manual therapy*, *19*(4), 324-330.

Licciardone, J. C., Kearns, C. M., Hodge, L. M. et Bergamini, M. V. W. (2012). Associations of Cytokine Concentrations With Key Osteopathic Lesions and Clinical Outcomes in

Patients With Nonspecific Chronic Low Back Pain: Results From the OSTEOPATHIC Trial. *The Journal of the American Osteopathic Association, 112*(9), 596-605. doi: 10.7556/jaoa.2012.112.9.596

Licciardone, J. C., Minotti, D. E., Gatchel, R. J., Kearns, C. M. et Singh, K. P. (2013). Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial. *The Annals of Family Medicine, 11*(2), 122-129.

O'Sullivan, P. (2005). Diagnosis and classification of chronic low back pain disorders: maladaptive movement and motor control impairments as underlying mechanism. *Manual therapy, 10*(4), 242-255.

Senna, M. K. et Machaly, S. A. (2011). Does maintained spinal manipulation therapy for chronic nonspecific low back pain result in better long-term outcome? *Spine, 36*(18), 1427-1437.

Wallwork, T. L., Stanton, W. R., Freke, M. et Hides, J. A. (2009). The effect of chronic low back pain on size and contraction of the lumbar multifidus muscle. *Manual therapy, 14*(5), 496-500.

Annexes

Annexe 1

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score=21.75

Section/Topic	Item No1	Checklist item: A randomized control trial to determine the effectiveness and physiological effects of spinal manipulation and spinal mobilization compared to each other and a sham condition in patients with chronic low back pain: Study protocol for The RELIEF Study	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.25
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5

	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	.5
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	.5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	0
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	.5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	.5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	0
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1

Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 2

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score = 20.5

Section/Topic	Item No2	Checklist item: **Associations of Cytokine Concentrations With Key Osteopathic Lesions and Clinical Outcomes in Patients With Nonspecific Chronic Low Back Pain: Results From the OSTEOPATHIC Trial**	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	0
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5

Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	.5
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	0
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	0

	11b	If relevant, description of the similarity of interventions	0
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	0
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	0
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	0
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1

Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 3

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score=24

Section/Topic	Item No3	Checklist itemChanges in biomechanical dysfunction and low back pain reduction with osteopathic manual treatment: Results from the OSTEOPATHIC Trial	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	0
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			

Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	.5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	1
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1

Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 4

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score: 24.5

Section/Topic	Item No4	Checklist item **Comparison of the Effectiveness of Three Manual Physical Therapy Techniques in a Subgroup of Patients With Low Back Pain Who Satisfy a Clinical Prediction Rule**	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5

	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	.5
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5
	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5

Statistical methods	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	0
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	.5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	1
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1

Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 5

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score:22.5

Section/Topic	Item No5	Checklist item **Does Maintained Spinal Manipulation Therapy for Chronic Nonspecific Low Back Pain Result in Better Long-Term Outcome?**	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	0
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5

	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5
	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5

Statistical methods	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	0
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	0
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1

Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 6

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score 24.5

Section/Topic	Item No6	Checklist item **Dose-response and efficacy of spinal manipulation for care of chronic low back pain: a randomized controlled trial**	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5

Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	.5
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	0
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	1
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			

Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 7

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score=17

Section/Topic	Item No7	Checklist item **Immediate effects of a high-velocity spine manipulation in paraspinal muscles activity of nonspecific chronic low-back pain subjects**	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	0
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5

Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	.5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	0
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	0
Allocation concealment mechanism	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	0
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	0
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	0
	11b	If relevant, description of the similarity of interventions	.5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	0
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	.5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	0
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	0
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1

Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	0

Annexe 8

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score=22

Section/Topic	Item No8	Checklist item **Immediate Effects of Region-Specific and Non–Region-Specific Spinal Manipulative Therapy in Patients With Chronic Low Back Pain: A Randomized Controlled Trial**	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	.5
	2b	Specific objectives or hypotheses	.5
Methods			

Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	.5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	0
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5

	11b	If relevant, description of the similarity of interventions	.5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	.5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	.5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	.5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	.5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	0
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	0

Annexe 9

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score:25

Section/Topic	Item No9	Checklist item Osteopathic Manual Treatment and Ultrasound Therapy for Chronic Low Back Pain: A Randomized Controlled Trial	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
	2a	Scientific background and explanation of rationale	.5

Background and objectives	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	.5
Randomisation:			.5
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	.5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	.5

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	.5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	.5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	.5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	.5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	1
Discussion			

Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 10

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score=25

Section/Topic	Item No 10	Checklist item Short-term effectiveness of spinal manipulative therapy versus functional technique in patients with chronic nonspecific low back pain: a pragmatic randomized controlled trial	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
	2a	Scientific background and explanation of rationale	.5

Background and objectives	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	.5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	.5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	.5

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	.5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	.5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	.5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	1
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

Annexe 11

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Total score: 23.5

Section/Topic	Item No 11	Checklist item Spinal Manipulative Therapy Has an Immediate Effect on Thermal Pain Sensitivity in People With Low Back Pain: A Randomized Controlled Trial	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	.5
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	.5
Introduction			
	2a	Scientific background and explanation of rationale	.5

Background and objectives	2b	Specific objectives or hypotheses	.5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	.5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	.5
Participants	4a	Eligibility criteria for participants	.5
	4b	Settings and locations where the data were collected	.5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	.5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	.5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	.5
Sample size	7a	How sample size was determined	.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	.5
Randomisation:			.5
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	.5
Allocation concealment mechanism	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	1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	.5
	11b	If relevant, description of the similarity of interventions	.5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	.5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	.5
	13b	For each group, losses and exclusions after randomisation, together with reasons	.5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	.5
	14b	Why the trial ended or was stopped	0
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	.5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	.5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	0
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1
Other information			1
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1