LC-OSTEO: where do we go from here?

JAMA Internal Medicine | Original Investigation

Effect of Osteopathic Manipulative Treatment vs Sham Treatment on Activity Limitations in Patients With Nonspecific Subacute and Chronic Low Back Pain

A Randomized Clinical Trial

Christelle Nguyen, MD, PhD[1,2,3]; Isabelle Boutron, MD, PhD; **Rafael Zegarra-Parodi, DO[4,5,6]** (French usage); Gabriel Baron, PhD; Sophie Alami, PhD; Katherine Sanchez, MD; Camille Daste, MD, MSc; Margaux Boisson, MD; **Laurent Fabre, DO[5]** (French usage); Peggy Krief, MD; **Guillaume Krief, DO[6]** (French usage); Marie-Martine Lefèvre-Colau, MD, PhD; Serge Poiraudeau, MD, PhD; François Rannou, MD, PhD[1,2,3]

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Programme Hospitalier de Recherche Clinique National 2011, Ministère de la Santé et des Solidarités (P110142, NCT02034864)

Paul Vaucher

Conflict of interest

- Registered osteopath in Switzerland
- Full Professor UAS, *University of Applied Sciences and Arts Western Switzerland*, Faculty of Health–Fribourg, Unit of Research on Mobility
- HES-SO Health Faculty Scientific Board, *member*
- COME – Centre for Osteopathic Medicine Collaboration, *member of the Board of Trustees*
- Mains Libres, *editor*

Christelle Nguyen

Conflict of interest

- **Academic position:** AP-HP, INSERM, Université de Paris
- **Academic fundings:** ANR, AP-HP, Arthritis Society, Association Française pour la Recherche Thermale, Canadian Institutes of Health Research, CNRS Libanais, Fondation Arthritis R&D, Fondation de l'Avenir, Fondation Paris Descartes, Groupe Francophone de Recherche sur la Sclérodermie, INSERM, Ministère des Solidarités et de la Santé, Programme Européen H2020, SATT Innov IDF, Université de Paris
- **Personal funding:** DRASS IDF, Fondation Bettencourt-Schueller, Laboratoire Expanscience, Société Française de Médecine Physique et de Réadaptation, Société Française de Rhumatologie
- **Interventions and expertises for industry:** Laboratoires Actelion, IPSEN, MEDA Pharma, Roche, Thuasne

Rafael Zegarra-Parodi

Conflict of interest

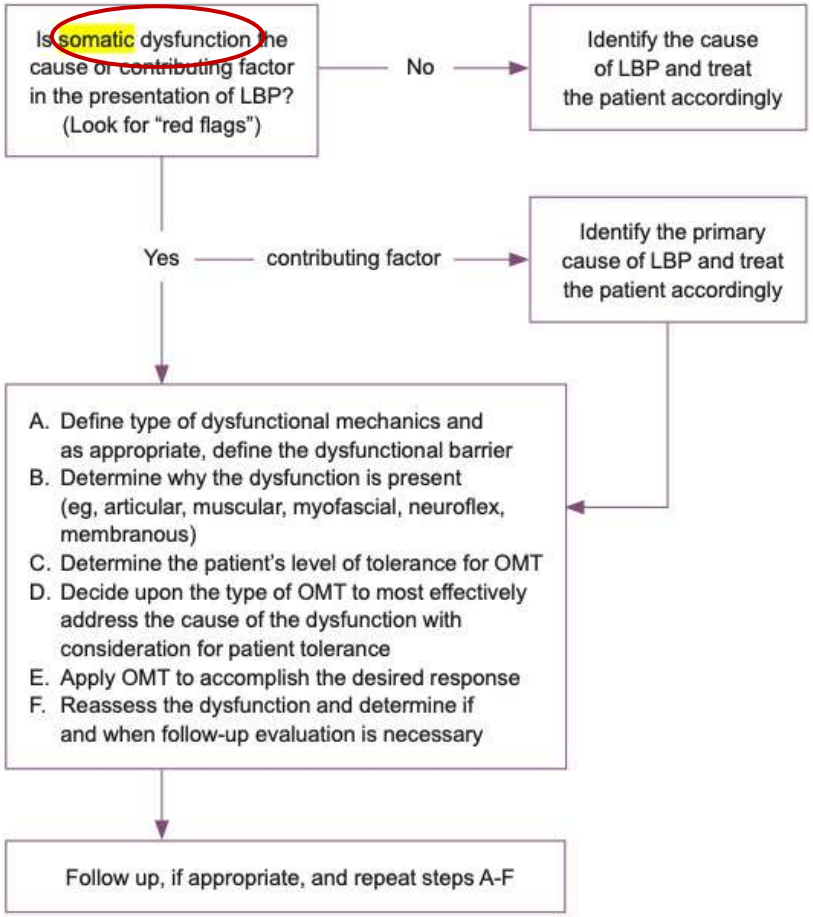
- Registered osteopath in France (ARS d'Île-de-France) and UK (#3418)
- A.T. Still Research Institute (USA), *research affiliate*
- Nonprofit foundation COME Collaboration (Italy), *member of the Board of Trustees*
- International Journal of Osteopathic Medicine (UK), *associate editor*
- BMS Formation (France), *cofounder & director*
- Lecturer at CEESO Paris (France), EOTS (Spain), HES-SO (Switzerland), Université Paris-Saclay (France)
- AP-HP, *co-supervision of the LC-OSTEO practitioners*

Outline

1. Osteopathic medicine & osteopathy
   1.1. French educational environment (*French decrees, 2014*)
   1.2. Osteopathic principles (1953 vs 2002)
2. Complex intervention methods to evaluate osteopathic care
3. LC-OSTEO: research question & design
4. LC-OSTEO: results & discussion
5. LC-OSTEO: possible perspectives
   5.1. Importance of contextual effects when applying osteopathic manipulative treatment (OMT) in osteopathic care
   5.2. Critical appraisal of traditional, body-centered models for osteopathic care
   5.3. Opportunity to develop evidence-informed, person-centered models for osteopathic care

American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain

Task Force on the Low Back Pain Clinical Practice Guidelines



«Once a patient with low back pain is diagnosed with somatic dysfunction as the cause of, or contributing factor to, low back pain, OMT should be utilized by the osteopathic physician.

The diagnosis of somatic dysfunction entails a focal or complete history and physical examination, including an osteopathic structural examination that provides evidence of asymmetrical anatomical landmarks, restriction or altered range of joint motion, and palpatory abnormalities of soft tissues.

Osteopathic manipulative treatment is used to manage somatic dysfunction after other potential causes of low back pain are ruled out or considered improbable by the treating physician.»

(Snow et al., 2016)

C1

You must be able to conduct an osteopathic patient evaluation and deliver safe, competent and appropriate osteopathic care to your patients.

1. This should include the ability to:
   - 1.1 take and record the patient's case history, adapting your communication style to take account of the patient's individual needs and sensitivities
   - 1.2 select and undertake appropriate clinical assessment of your patient, taking into account the nature of their presentation and their case history
   - 1.3 formulate an appropriate working diagnosis or rationale for care and explain this clearly to the patient
   - 1.4 develop and apply an appropriate plan of treatment and care; this should be based on:
     - 1.4.1 the working diagnosis
     - 1.4.2 the best available evidence
     - 1.4.3 the patient's values and preferences
     - 1.4.4 your own skills, experience and competence
   - 1.5 adapt an osteopathic technique or treatment approach in response to findings from the examination of your patient
   - 1.6 evaluate post-treatment response and justify the decision to continue, modify or cease osteopathic treatment as appropriate
   - 1.7 recognise adverse reactions to treatment, and take appropriate action
   - 1.8 monitor the effects of your care, and keep this under review; you should cease care if requested to do so by the patient or if you judge that care is likely to be ineffective or not in the patient's best interests
   - 1.9 recognise when errors have been made, and take appropriate action to remedy these, taking account of the patient's best interests under your duty of candour (see standard D3)
   - 1.10 where appropriate, refer the patient to another healthcare professional, following appropriate referral procedures.

MINISTÈRE DES AFFAIRES SOCIALES, DE LA SANTÉ ET DES DROITS DES FEMMES

SANTÉ

PROFESSIONS DE SANTÉ

MINISTÈRE DES AFFAIRES SOCIALES,
DE LA SANTÉ
ET DES DROITS DES FEMMES

Arrêté du 12 décembre 2014
relatif à la formation en ostéopathie (*JO*RF n° 0289 du 14 décembre 2014)

NOR : *AFSH1426478A*

Legal definitions in France

- Profession: «The osteopath, in a systemic approach, after osteopathic diagnosis, performs mobilizations and manipulations for the management of osteopathic dysfunctions in the human body. These manipulations and mobilizations aim to prevent or remedy dysfunctions in order to maintain or improve the state of health of people.»

- Osteopathic technique: «set of gestures based on osteopathic principles»

Osteopathic principles *(Evans, 2013)*

Table 1 The three consensus borne 'sets' of osteopathic principles.

1922 principles[2]	1953 principles[3]	2002 principles[4]
The osteopathic view of the cell, whether as a unit or as one of the millions making up the human body, is largely covered by the following statements: 1. *Normal structure is essential to normal function* 2. *Normal function is essential if normal structure is to be maintained* 3. *Normal environment is essential to normal function and structure, though some degree of adaptation is possible for a time, even under abnormal conditions* In the human body, with its diversified	1. *The body is a unit* 2. *The body possesses self-regulatory mechanisms* 3. *Structure and function are reciprocally interrelated* 4. *Rational therapy is based on an understanding of body unity, self-regulatory mechanisms, and the interrelationship of structure and function*	Revised tenets of osteopathic medicine 1. *A person is the product of dynamic interaction between body, mind, and spirit* 2. *An inherent property of this dynamic interaction is the capacity of the individual for the maintenance of health and recovery from disease* 3. *Many forces, both intrinsic and extrinsic to the person, can challenge this inherent capacity and contribute to the onset of illness* 4. *The musculoskeletal system*

BO Santé – Protection sociale – Solidarité n° 2014/11 du 15 décembre 2014, Page 57

Educational recommendations

Osteopathic principles and foundations will be critically appraised and updated based on the best available evidence.

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Different types of evaluations

- Osteopathic manipulation
  - Evaluation of associated physiological effects
- Osteopathic manipulative treatment (OMT)
  - Evaluation of the specific manual component of osteopathic care
- Osteopathic care
  - Evaluation of the whole interaction between the patient and osteopathic practitioner: OMT & contextual effects

Current limitations when evaluating OMT by 1953 body-centered osteopathic principles?

RANDOMIZED TRIAL

Osteopathic Manipulative Treatment for Chronic Low Back Pain

A Randomized Controlled Trial

Licciardone, John C. DO[*]; Stoll, Scott T. DO[†]; Fulda, Kimberly G. MPH[*]; Russo, David P. DO[‡]; Siu, Jeff BA[†]; Winn, William DO[§]; Swift, Jon Jr, DO[‖] Author Information

Spine: July 1, 2003 - Volume 28 - Issue 13 - p 1355-1362
doi: 10.1097/01.BRS.0000067110.61471.7D

Conclusions.

Osteopathic manipulative treatment and sham manipulation both appear to provide some benefits when used in addition to usual care for the treatment of chronic nonspecific low back pain. It remains unclear whether the benefits of osteopathic manipulative treatment can be attributed to the manipulative techniques themselves or whether they are related to other aspects of osteopathic manipulative treatment, such as range of motion activities or time spent interacting with patients, which may represent placebo effects.

Current limitations when evaluating specific effects of manual procedures?

Aspinall et al. Chiropractic & Manual Therapies (2019) 27:7
https://doi.org/10.1186/s12998-018-0226-7

Chiropractic & Manual Therapies

SYSTEMATIC REVIEW Open Access

Manipulation-induced hypoalgesia in musculoskeletal pain populations: a systematic critical review and meta-analysis

Sasha L. Aspinall[1*], Charlotte Leboeuf-Yde[1,2], Sarah J. Etherington[3] and Bruce F. Walker[1]

- Best level of available evidence
- Systemic manipulation-induced hypoalgesia in musculoskeletal pain populations
- No significant differences when compared with sham manipulation

- Patients cannot perceive a difference between what practitioners describe as a «placebo» and a «real» manual procedure.

Different methods to evaluate OMT in clinical trials

- Standardized treatment
- Semi-standardized treatment
- «Black box» treatment
- Problems generalizing the results to inform osteopathic practice
- LC-OSTEO (Lombalgie Chronique – Ostéopathie): a specific design to describe OMT through the use of a complex intervention methodology to improve the quality of the RCT

4 Basic methodological differences

Methodological Differences in Clinical Trials Evaluating Nonpharmacological and Pharmacological Treatments of Hip and Knee Osteoarthritis

Isabelle Boutron, MD
Florence Tubach, MD
Bruno Giraudeau, PhD
Philippe Ravaud, MD, PhD

Context Randomized controlled trials have been developed essentially in the context of pharmacological treatments (ie, oral drugs; intra-articular injection; and topical, intramuscular, and intravenous treatments), but assessment of the effectiveness of nonpharmacological treatments (ie, surgery, arthroscopy, joint lavage, rehabilitation, acupuncture, and education) presents specific issues.

110 papers: 50 nonpharmacological trials vs 60 pharmacological trials

- Lower methodological quality (according to the Jadad scale)
- Incomplete reporting of methods (randomization, analysis, adverse events)
- Problems with placebo and blinding (patients, assessors, practitioners)
- Influence of the level of training of practitioners on outcome measures

(Boutron et al., 2003)

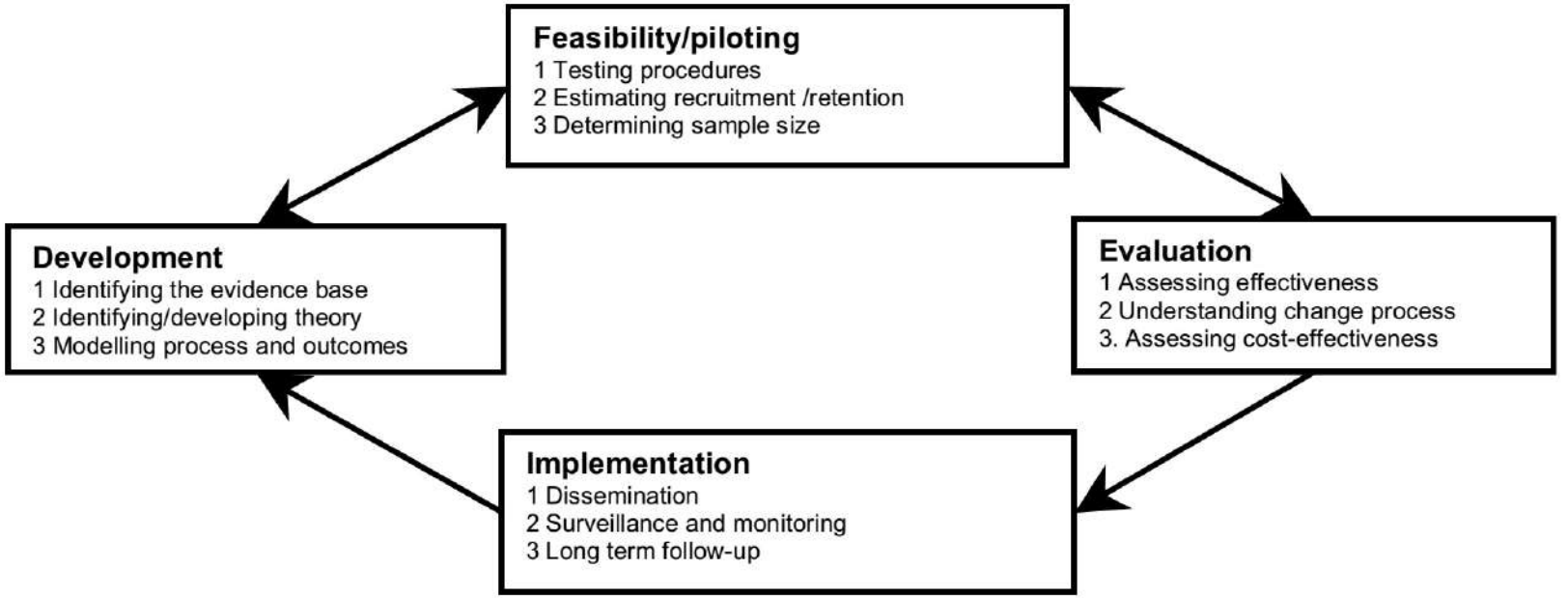
Things to consider when designing and planning the clinical trial

MRC Medical Research Council

Developing and evaluating complex interventions:

Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019.

Figure 1 Key elements of the development and evaluation process



(Medical Research Council Guidelines, 2006)

Things to consider when reporting the results

RESEARCH AND REPORTING METHODS **Annals of Internal Medicine**

CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts

Isabelle Boutron, MD, PhD; Douglas G. Altman, DSc; David Moher, PhD; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT NPT Group*

- LC-OSTEO: a 45-page appendix transparently reporting interventions and methods
- Challenges: understanding and replicability of the interventions and methodological choices (always debatable!)

(Boutron et al., 2017)

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LC-OSTEO *(Nguyen et al., 2021)*

IMPORTANCE Osteopathic manipulative treatment (OMT) is frequently offered to people with nonspecific low back pain (LBP) but never compared with sham OMT for reducing LBP-specific activity limitations.

OBJECTIVE To compare the efficacy of standard OMT vs sham OMT for reducing LBP-specific activity limitations at 3 months in persons with nonspecific subacute or chronic LBP.

LC-OSTEO: evaluation in line with current standards of osteopathic care

- OMT group
  - One standard (= usual care) of OMT (= not standardized)
  - Individualized OMT based on diagnosis of somatic dysfunction (*AOA guidelines for OMT for patients with LBP, 2016*)

- Sham OMT group
  - Placebo of OMT (light touch)
  - Standardized, not individualized

LC-OSTEO: evaluation in line with current osteopathic care

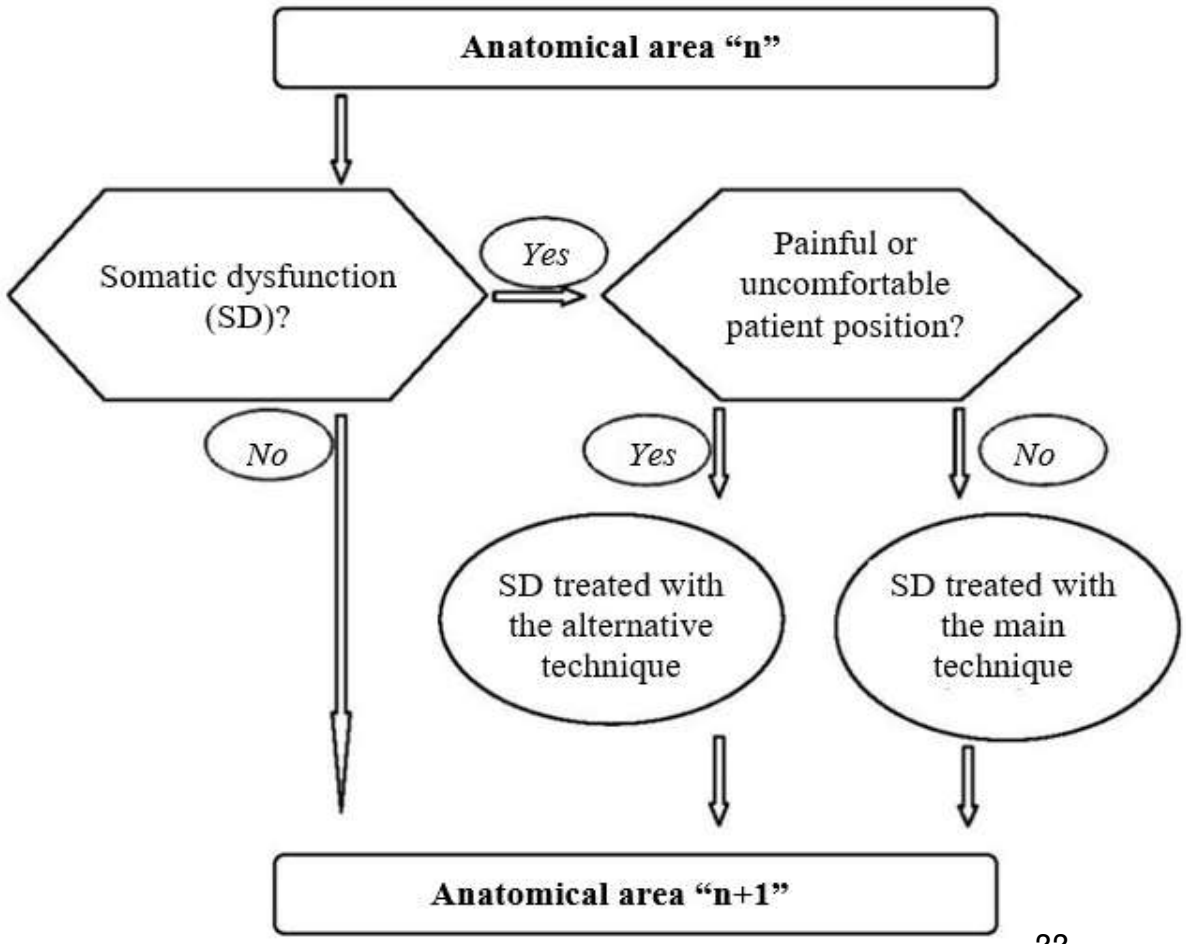
Consultations 45 minutes	Standard OMT	Sham OMT
Therapeutic context **10 ± 2 minutes**	Standardized procedures to ensure a similar therapeutic alliance (e.g., overall verbalization, quality of listening and dialogue, empathy, and trust for a favorable outcome of symptoms). Patients blinded to «osteopathic treatment»: received a standardized explanatory model of «manual therapy.»	
Diagnostic procedures **10 ± 2 minutes**	Standardized osteopathic clinical examination of the whole musculoskeletal system and abdomen	
Therapeutic tailoring, procedures, and application **15 ± 2 minutes**	○ Yes. Osteopathic clinical examination information included when deciding whether to apply a technique. ○ 7 Different manual techniques applied over 7 anatomical areas ○ Face-to-face, individual session with practitioners following intention-to-treat standards	○ No. Same standardized sham treatment applied without including osteopathic clinical examination information during the process. ○ A single manual technique applied over the entire musculoskeletal system and abdomen *(Noll et al, 2010)* ○ Face-to-face, individual session with the practitioner's attention distracted (silent backwards counting)
Clinical recordings **4 minutes**	Osteopathic clinical form filled out at the end of each session. Specific techniques used were recorded.	Osteopathic clinical form filled out at the end of each session. Standardized sham treatment recorded.
Therapeutic dosage	Total of 6 sessions at 2-week intervals	
Practitioner characteristics	• Osteopathic practitioners legally registered in France who graduated from a 5-year full-time training program without previous medical or paramedical training. Formal assessment with 3 certifying osteopathic practitioners after 2 days of training to become practitioners for this study.	

Individualized treatment in the OMT group: decision algorithm based on the osteopath's clinical examination

Osteopathic diagnosis (somatic dysfunction)

- Skills most commonly described by osteopaths in the scientific literature, the AOA Guidelines, and the French decrees
- Methods of complex interventions
- Individualized, practitioner-dependent osteopathic care in the OMT group

Decision algorithm for the techniques according to the presence of somatic dysfunction and patient pain/discomfort

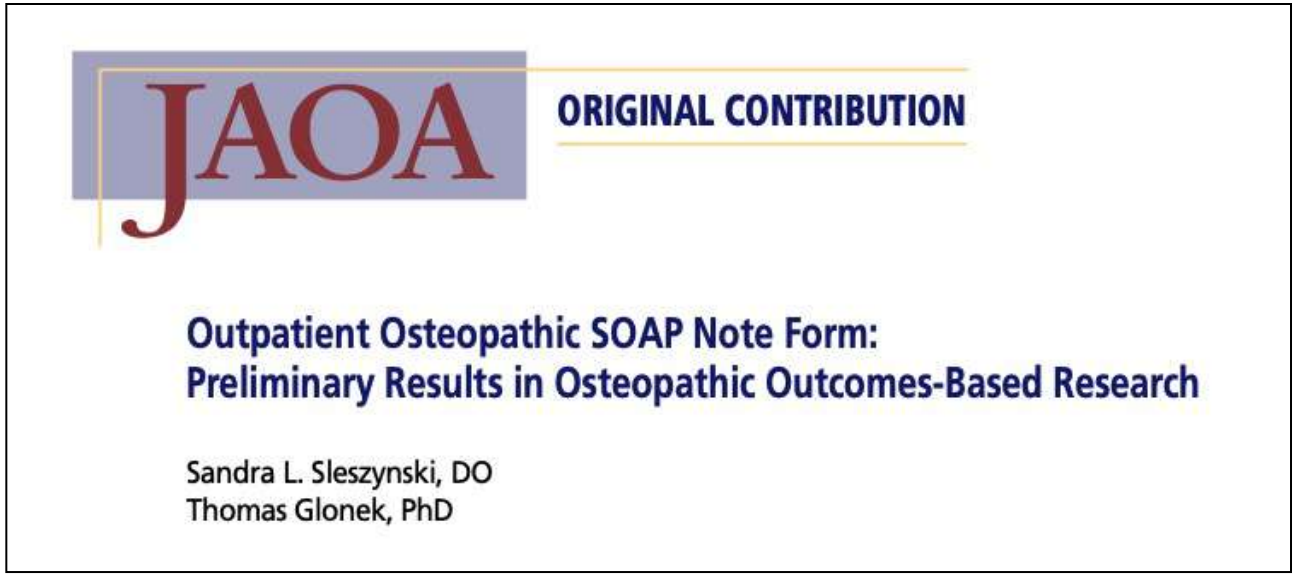


OMT group: 7 anatomical areas as described in the scientific literature *(Sleszynski and Glonek, 2015)*

Table 9
SOAP Note Form* Outcomes Research:
Number of Body Regions Treated with OMT (N=3908)

Body Regions Treated Per Subject	Subjects Receiving OMT, No (%)
0	7 (0.2)
1 to 2	160 (5.1)
3 to 4	468 (14.9)
5 to 6	648 (20.6)
7 to 8	1130 (35.9)
9 to 10	734 (23.3)
Total	**3147† (100)**

* *SOAP Note Form* indicates Outpatient Osteopathic SOAP (Subjective, Objective, Assessment, Plan) Note Form; *OMT*, osteopathic manipulative treatment.
† The difference between subject population (3908) and the total number of subjects receiving OMT (3147), as indicated by body regions treated, indicates that not all subjects' SOAP Note Forms included documentation of OMT by body region.


JAOA

ORIGINAL CONTRIBUTION

Outpatient Osteopathic SOAP Note Form:
Preliminary Results in Osteopathic Outcomes-Based Research

Sandra L. Sleszynski, DO
Thomas Glonek, PhD

Sham OMT group: the use of light touch
(Noll et al., 2010)

Noll *et al. Osteopathic Medicine and Primary Care* 2010, **4**:2
http://www.om-pc.com/content/4/1/2

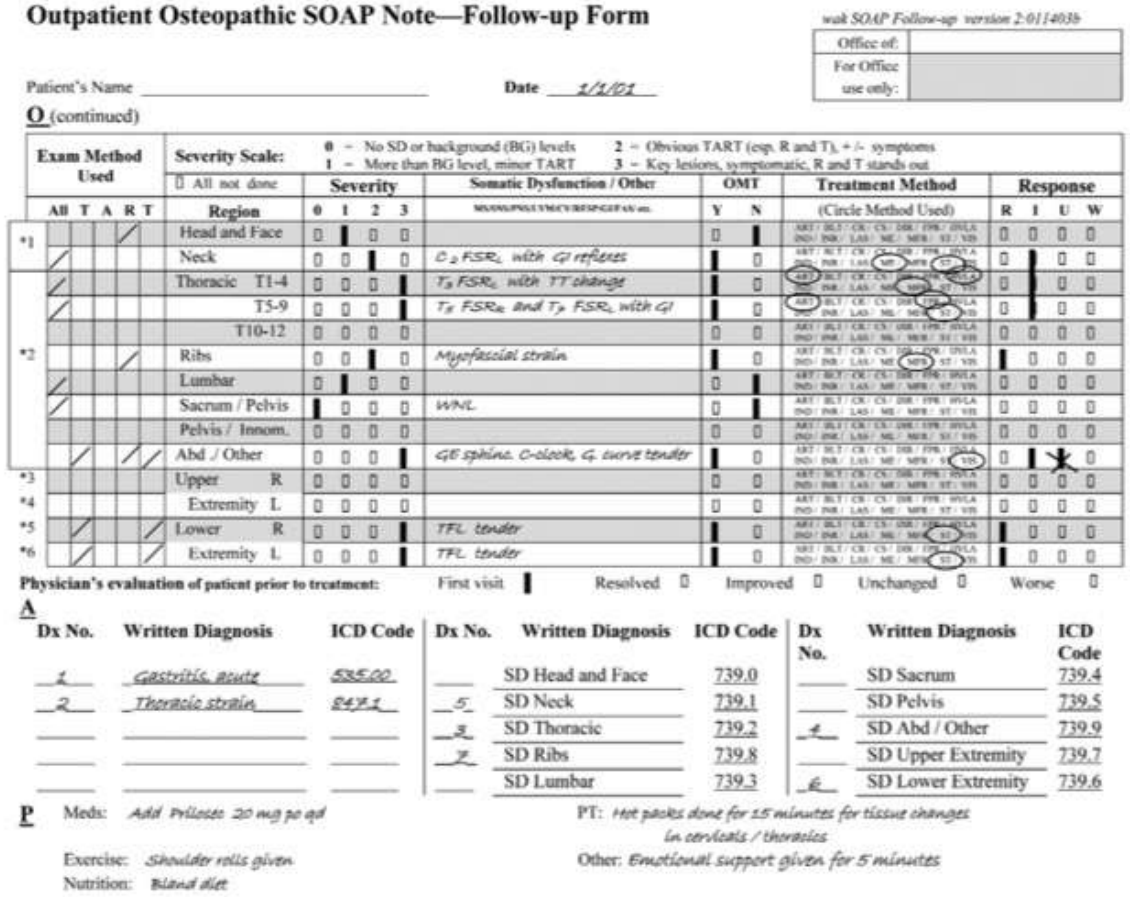
RESEARCH Open Access

Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial

Donald R Noll[1*], Brian F Degenhardt[2], Thomas F Morley[3], Francis X Blais[4], Kari A Hortos[5], Kendi Hensel[6], Jane C Johnson[2], David J Pasta[7], Scott T Stoll[8]

Osteopathic data collection tool: the Outpatient Osteopathic SOAP Note Form

(Sleszynski and Glonek, 2015)



Outpatient Osteopathic SOAP Note—Follow-up Form

wak SOAP Follow-up version 2.011403b

Office of:
For Office use only:

Patient's Name _____ Date 1/1/01

O (continued)

Exam Method Used: All T A R T	Region	Severity 0 1 2 3	Somatic Dysfunction / Other	OMT Y N	Treatment Method (Circle Method Used)	Response R I U W
*1	Head and Face					
	Neck		C 2 FSR, with GI reflexes			
	Thoracic T1-4		T3 FSR, with TT change			
	T5-9		T6 FSR, and T9 FSR, with GI			
	T10-12					
*2	Ribs		Myofascial strain			
	Lumbar					
	Sacrum / Pelvis		WNL			
	Pelvis / Innom.					
	Abd / Other		GE sphinc. C-clock, G. curve tender			
*3	Upper R					
*4	Extremity L					
*5	Lower R		TFL tender			
*6	Extremity L		TFL tender			

Severity Scale: 0 = No SD or background (BG) levels; 1 = More than BG level, minor TART; 2 = Obvious TART (esp. R and T), +/- symptoms; 3 = Key lesions, symptomatic, R and T stands out. ☐ All not done

Physician's evaluation of patient prior to treatment: First visit ▮ Resolved ☐ Improved ☐ Unchanged ☐ Worse ☐

A

Dx No.	Written Diagnosis	ICD Code
1	Gastritis, acute	535.00
2	Thoracic strain	847.2

Dx No.	Written Diagnosis	ICD Code
	SD Head and Face	739.0
5	SD Neck	739.1
3	SD Thoracic	739.2
7	SD Ribs	739.8
	SD Lumbar	739.3

Dx No.	Written Diagnosis	ICD Code
	SD Sacrum	739.4
	SD Pelvis	739.5
4	SD Abd / Other	739.9
	SD Upper Extremity	739.7
6	SD Lower Extremity	739.6

P Meds: Add Prilosec 20 mg po qd

Exercise: Shoulder rolls given

Nutrition: Bland diet

PT: Hot packs done for 15 minutes for tissue changes in cervicals / thoracics

Other: Emotional support given for 5 minutes

JAOA ORIGINAL CONTRIBUTION

Outpatient Osteopathic SOAP Note Form: Preliminary Results in Osteopathic Outcomes-Based Research

Sandra L. Sleszynski, DO
Thomas Glonek, PhD

Methods: design and participants

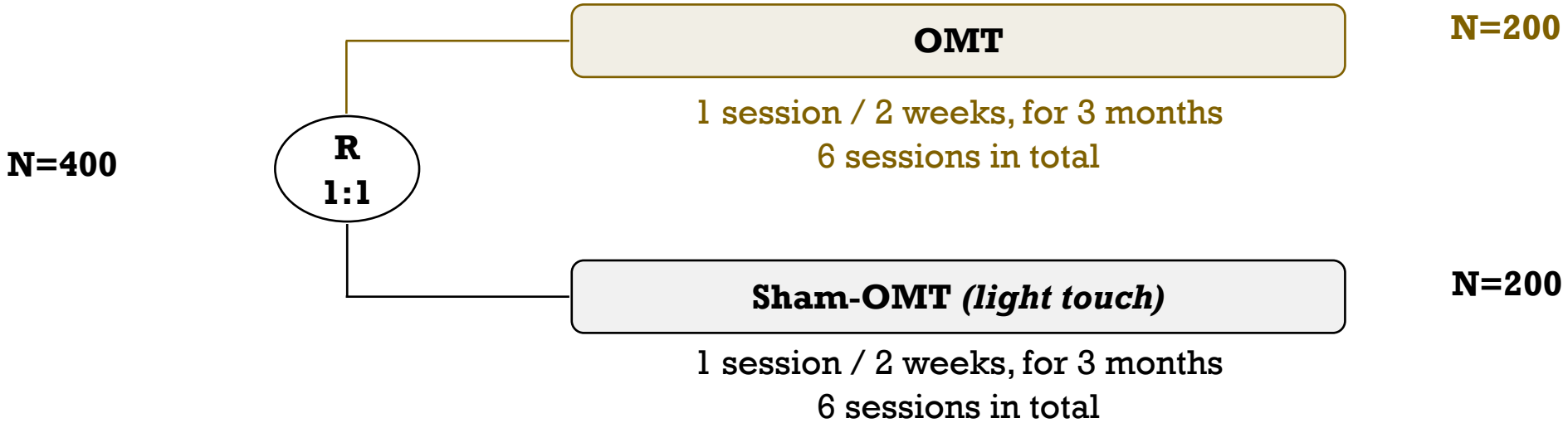
- **Design**
  - Prospective, 2 parallel arms, randomized, controlled, monocentric, and single-blinded (participants)
  - Trial conducted from February 17, 2014 to October 23, 2017

- **Recruitment**
  - Service de Rééducation et de Réadaptation de l'Appareil Locomoteur et des Pathologies du Rachis, Cochin
  - Consultations, hospitalizations, and announcement campaign for AP-HP (Assistane Publique – Hôpitaux de Paris) professionals

Main inclusion criteria
- 18 to 65 years old
- Nonspecific low back pain (LBP)
- LBP duration ≥ 6 weeks

Main exclusion criteria
- Specific LBP
- Spinal surgery in previous 6 months
- Motor deficit
- Pregnancy
- Manual therapists

Methods: interventions and outcomes



Main outcome	Mean change in Quebec Back Pain Disability Index (QBPDI) (0, no disability to 100, maximal disability)	M3
Secondary outcomes	Mean change in QBPDI	M12
	Mean change in back pain	M3 and M12
	Mean change in health-related quality of life (SF-12)	M3 and M12
	Analgesics and NSAIDs consumption	M3 and M12
	Duration and number of sick leaves	M12
	Number of acute back pain episodes	M12
Collected variables (no between-group comparisons)	Credibility of interventions	M3
	Verbal communication during sessions	M3
	Adverse events	M3, M6 and M12
	Co-interventions	M3, M6 and M12

Methods: standardization of interventions

- **Osteopathic practitioners:** registered with the Répertoire National de la Certification Professionnelle

- **Standardized training:** 2 days of training followed by a formal assessment

- **Measures to reduce single-blind bias**
  - Prohibition on using the word "osteopathy" in advertisements and during sessions
  - Not seeing patients outside the study
  - Audio recording of the sessions and qualitative analysis of 60 randomly selected recordings
  - Credibility check of interventions at 3 month (M3): credibility/expectancy questionnaire

- **Sessions:** 45 minutes, 3 steps
  - Case history**:** location of pain
  - Osteopathic examination**:** entire musculoskeletal system and abdomen
  - Manipulation**:** OMT or sham OMT (light touch)

Methods: analysis

- **Hypothesis:** difference in the variation of the Quebec score at 3 months between the 2 groups, specifically 7 points out of 100 Minimal Clinically Important Difference (MCID) with a size effect of 0.35 (risk α of 5% and power of 90%)

- **Descriptive analysis**
  - Qualitative variables: absolute and relative frequencies
  - Quantitative variables: mean (SD) or median (Q1-Q3)

- **Comparative analysis:** conducted on an intention-to-treat basis
  - Variations in scores: constrained model of longitudinal data analysis
  - Consumption of analgesics and nonsteroidal anti-inflammatory drugs: Poisson model
  - Duration and number of work stoppages and episodes of acute pain: negative binomial regression

- **Bilateral tests:** $P < .05$ considered statistically significant

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Results

Research

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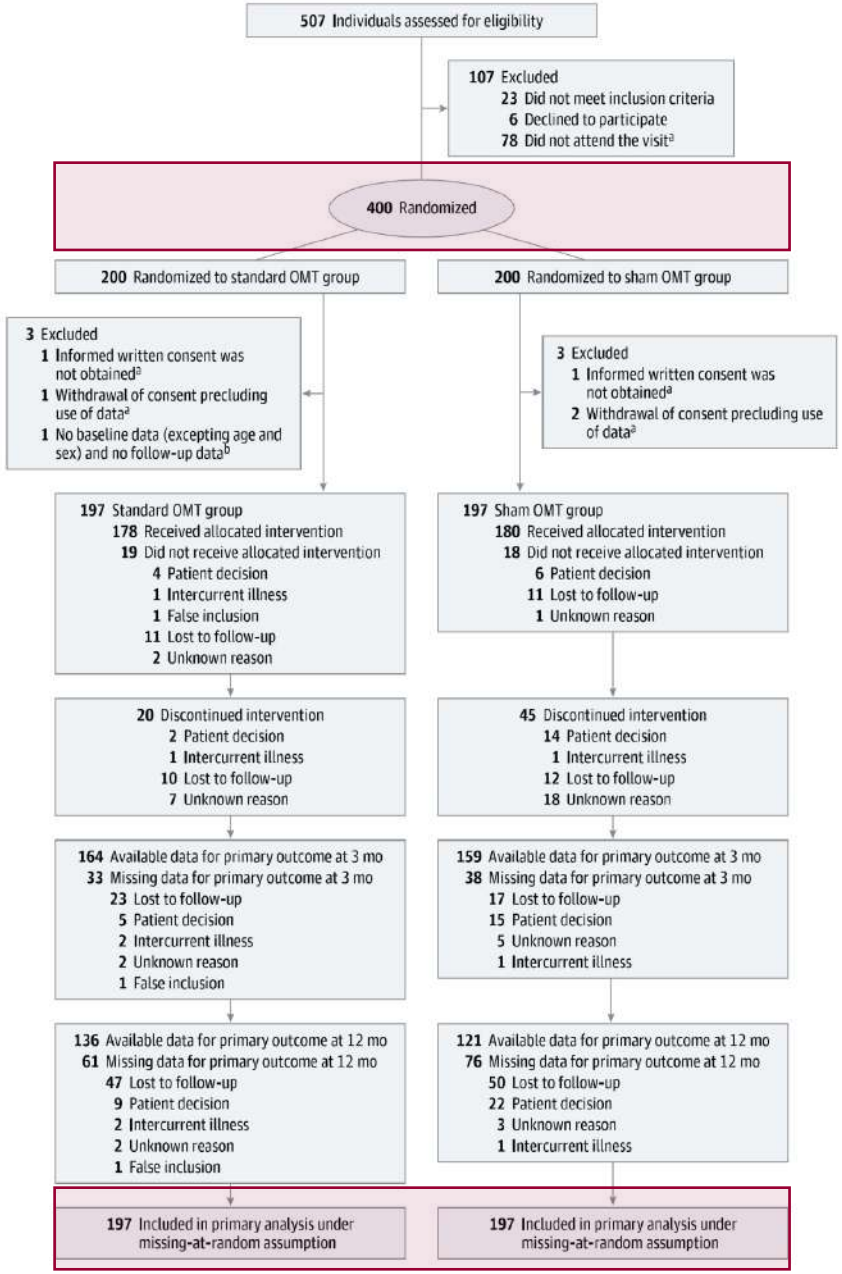
Results: flow chart



Recruitment

Allocation

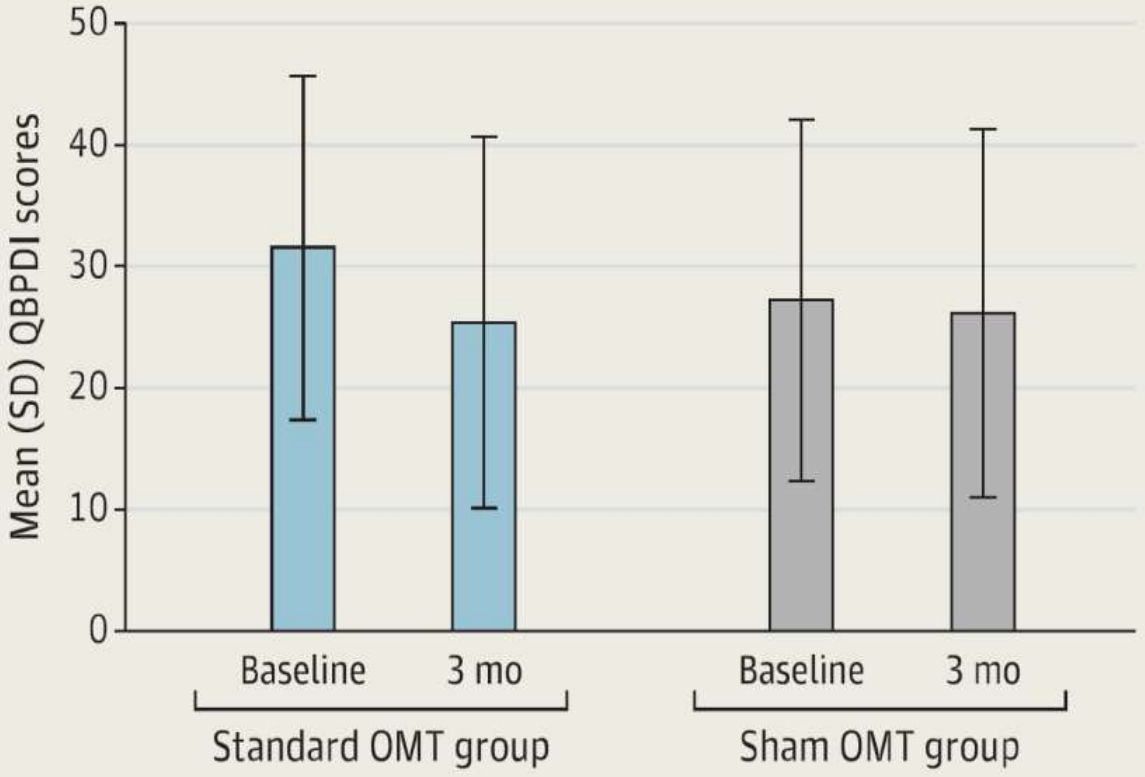
Follow-up

Analysis

Results: participants

Characteristics	Standard OMT (n = 197)	Sham OMT (n = 197)
Mean age (SD) - yr	48.3 (11.9)	47.5 (10.6)
Female - no./total no. (%)	116/197 (58.9)	119/197 (60.4)
Higher education - no./total no. (%)	**132/196 (67.3)**	**128/197 (65.0)**
Currently working - no./total no. (%)	**175/196 (89.3)**	**184/197 (93.4)**
Mean current LBP episode duration (SD) - months	**6.5 (10.3)**	**8.5 (17.2)**
Mean LBP pain intensity on NRS (SD) (range, 0 to 100)	**42.0 (21.1)**	**41.4 (21.5)**
Mean QBPDI score (SD) (range, 0 to 100)	**31.5 (14.1)**	**27.2 (14.8)**
Mean MOS SF-12 score		
Physical component summary (range, 9.95 to 70.02)	40.2 (8.2)	41.9 (7.8)
Mental component summary (range, 5.89 to 71.97)	42.9 (10.9)	42.7 (10.7)
Previous treatments - no./total no. (%)		
Analgesics	173/188 (92.0)	172/193 (89.1)
Non-opioids	167/188 (88.8)	170/193 (88.1)
Weak opioids†	124/188 (66.0)	113/193 (58.5)
Strong opioids†	21/188 (11.2)	17/193 (8.8)
Non-steroidal anti-inflammatory drugs	160/188 (85.1)	157/193 (81.3)
Antiepileptics	15/188 (8.0)	8/193 (4.1)
Spinal corticosteroid injections	55/188 (29.3)	38/193 (19.7)
Lumbar brace	125188 (66.5)	119/193 (61.7)
Outpatient physiotherapy	146/188 (77.7)	140/193 (72.5)
Alternative medicine	**100/188 (53.2)**	**104/193 (53.9)**

Results: main outcome



Mean Reduction in LBP-Specific Activity Limitations

Standard OMT: −4.7 (95% CI, −6.6 to −2.8)

Sham OMT: −1.3 (95% CI, −3.3 to 0.6)

Difference: −3.4 (95% CI, −6.0 to −0.7); *P* = .01

Results: secondary outcomes

Outcome	Standard OMT (n = 197)	Sham OMT (n = 197)	Absolute difference (95% CI)	Relative Risk or Ratio of Means (95% CI)	p-value
3 months after randomization					
Mean change in LBP intensity	**-8.1 (-11.5; -4.7)**	**-7.1 (-10.5; -3.7)**	**-1.0 (-5.5; 3.5)**	**-**	**0.66**
Mean change in PCS of SF-12	4.1 (3.0; 5.3)	3.6 (2.4; 4.8)	0.5 (-1.0; 2.1)	-	0.51
Mean change in MCS of SF-12	1.7 (0.3; 3.1)	1.2 (-0.2; 2.6)	0.5 (-1.4; 2.4)	-	0.60
Analgesics - no./total no. (%)	49/162 (30.3)	39/154 (25.3)	4.9 (-6.7; 16.5)	1.2 (0.8; 1.8)	0.41
NSAIDs - no./total no. (%)	29/169 (18.0)	31/158 (19.6)	-1.6 (-11.1; 7.9)	0.9 (0.6; 1.5)	0.74
12 months after randomization					
Mean change in QBPDI	**-5.6 (-7.9; -3.3)**	**-1.3 (-3.7; 1.2)**	**-4.3 (-7.6; -1.0)**	**-**	**0.01**
Mean change in LBP intensity	**-8.3 (-12.1; -4.5)**	**-6.3 (-10.3; -2.3)**	**-2.0 (-7.2; 3.3)**	**-**	**0.47**
Mean change in PCS of SF-12	4.2 (2.7; 5.6)	2.5 (1.0; 3.9)	1.7 (-0.3; 3.6)	-	0.09
Mean change in MCS of SF-12	1.4 (-0.2; 3.1)	2.5 (0.8; 4.2)	-1.1 (-3.3; 1.2)	-	0.35
Analgesics - no./total no. (%)	43/129	35/117 (29.9)	3.4 (-10.6; 17.5)	1.1 (0.7; 1.8)	0.63
NSAIDs - no./total no. (%)	21/135	25/120 (20.8)	-5.3 (-15.8; 5.3)	0.7 (0.4; 1.3)	0.32
Mean sick leave duration - days	5.6 (19.3)	4.4 (16.5)	1.0 (-3.2 ; 5.3)	1.4 (0.4; 4.6)	0.58
Mean number of sick leaves	0.3 (0.7)	0.2 (0.5)	-0.0 (-0.2 ; 0.2)	1.4 (0.7; 2.5)	0.32
Mean number of LBP episodes	11.8 (17.5)	14.8 (19.9)	-3.0 (-7.7 ; 1.8)	0.8 (0.6; 1.0)	0.08

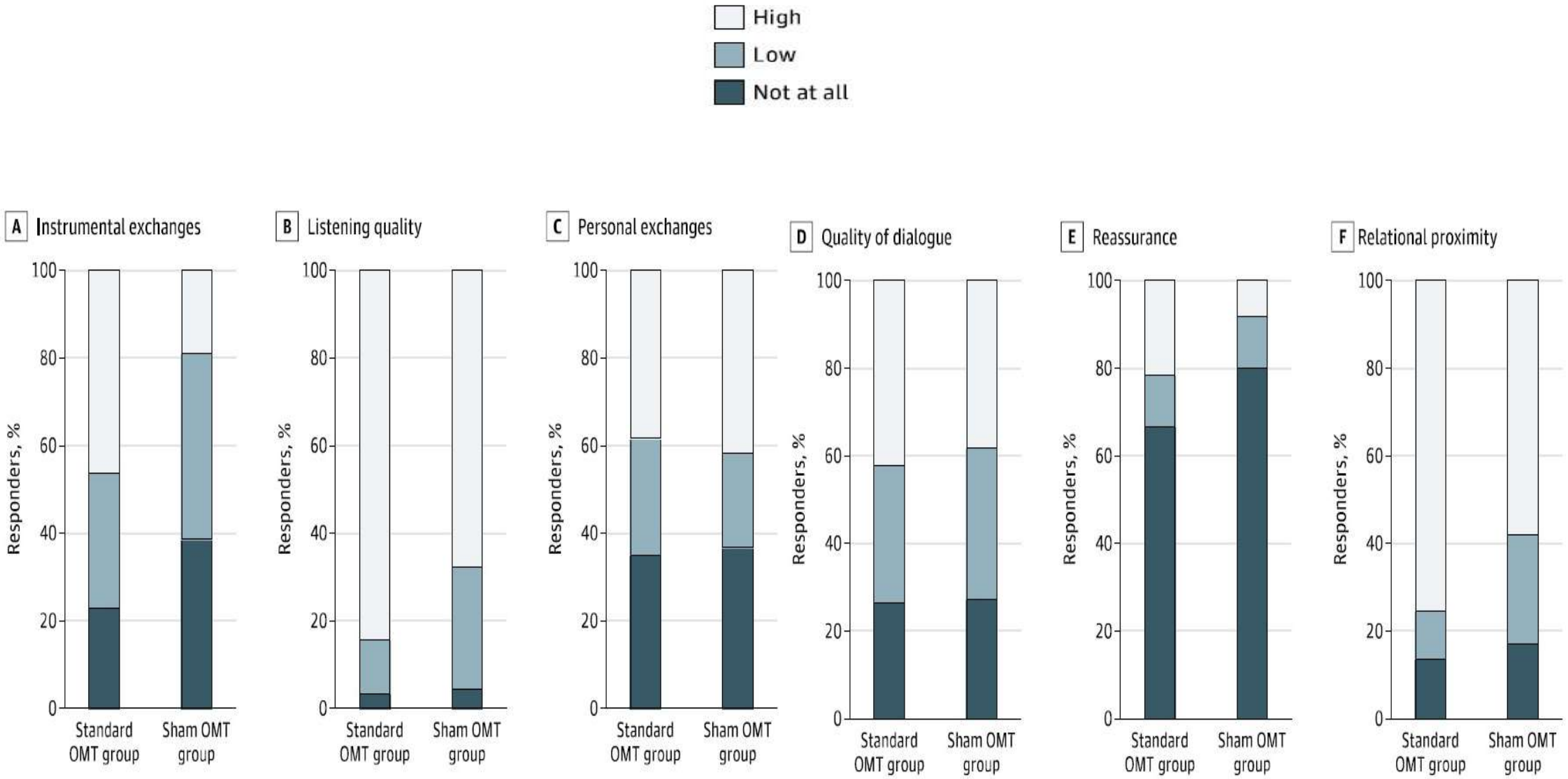
Results: adverse events

Adverse events	Standard OMT	Sham OMT
Serious	**4**	**8**
• Fracture	0	3
• Pregnancy	2	0
• Surgery	1	3
• Cancer	0	1
• Hospitalization in psychiatry	1	0
• Increased low back pain	0	1
Minor	**176**	**145**
• **Increased low back pain**	**51**	**35**
• **Joint pain**	**21**	**28**
• **Other musculoskeletal pain**	**22**	**16**
• **Radiculalgia**	**11**	**4**
• **Digestive symptoms**	**14**	**7**
• Cardiorespiratory symptoms	9	7
• Neurological symptoms	8	8
• Anxiety / depression / insomnia	5	2

Results: credibility and expectations

Questions (0 = not at all, to 9 = totally agree)	Standard OMT	Sham OMT
At this point, how logical does the group therapy offered to you seem? (1 [not logical] to 9 [very logical])	**6.7 (2.0)**	4.9 (2.2)
At this point, how useful do you think this treatment will be in reducing your symptoms? (1 [not useful] to 9 [very useful])	**6.4 (2.1)**	4,6 (2.2)
How confident would you be in recommending this treatment to a friend who experiences similar problems? (1 [not confident] to 9 [very confident])	**6.9 (2.3)**	4.8 (2.5)
By the end of the therapy period, how much improvement in your symptoms would you expect? (1 [no improvement] to 9 [total improvement])	**5.9 (2.1)**	4.5 (2.3)
At this point, how much do you really feel that therapy will help you to reduce your symptoms? (1 [not at all] to 9 [totally])	**6.2 (2.0)**	4.8 (2.3)
By the end of the therapy period, how much do you really feel that therapy helped you to improve your symptoms? (1 [not at all] to 9 [totally])	**5.9 (2.2)**	4.5 (2.4)

Results: verbal communication



Discussion: a questionable clinical relevance

- **Differences in variations observed between the 2 groups (in favor of OMT)**
  - Quebec score: **-3,4 points out of 100** at M3 and **-4,3 points out of 100** at M12
  - LBP: **-1,0 points out of 100** at M3 and **-2,0 points out of 100** at M12

- **MCID *(Ostelo et al., 2008; Daste et al., 2020)***
  - Quebec score: **-20 points out of 100**
  - LBP: **-30 points out of 100**
  - Post hoc analysis on binary response criteria **(Change Quebec score ≥ 20 points)**
    - Percentage of responders in the OMT group: **10%**
    - Percentage of responders in the sham OMT group: **8%**
    - Absolute risk difference: **3% (IC à 95% -4 à 9%)**

- **➔ Observed differences not clinically relevant**

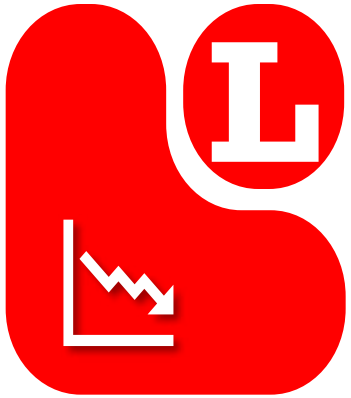
Discussion: non-specific effects

- **Practitioner/participant relationships and practitioner attitudes towards the patient**
  - Imbalance of credibility: failure of the blinding? Imbalance in effectiveness?
  - Imbalance in verbal communication
- **Imbalance of « treated » anatomic areas**

Areas treated	Standard OMT	Sham OMT
Lumbar spine	890/947 (94)	889/891 (99)
Root of mesentery	836/944 (89)	889/891 (99)
Diaphragm	799/926 (86)	889/891 (99)
Atlanto-occipital joint	749/925 (81)	889/891 (99)
Sacroiliac joint	554/910 (61)	889/891 (99)
Temporomandibular joint	482/912 (53)	889/891 (99)
Talocrural joint	468/912 (51)	889/891 (99)

- **Could explain up to 66% of the variance of symptoms in LBP patients *(Menke et al., 2014)***

Discussion: strengths and limitations



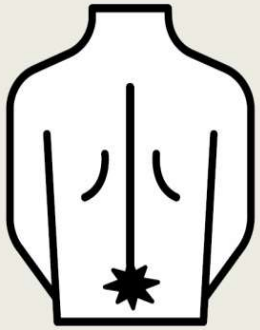
- Large sample size
- Control of nonspecific effects

- Monocentric study
- One standard intervention

Take-home message

POPULATION

159 Men, 235 Women



Adults with nonspecific subacute and chronic low back pain (LBP)

Median (range) age, 49.8 (40.7-55.8) y

INTERVENTION

400 Participants randomized

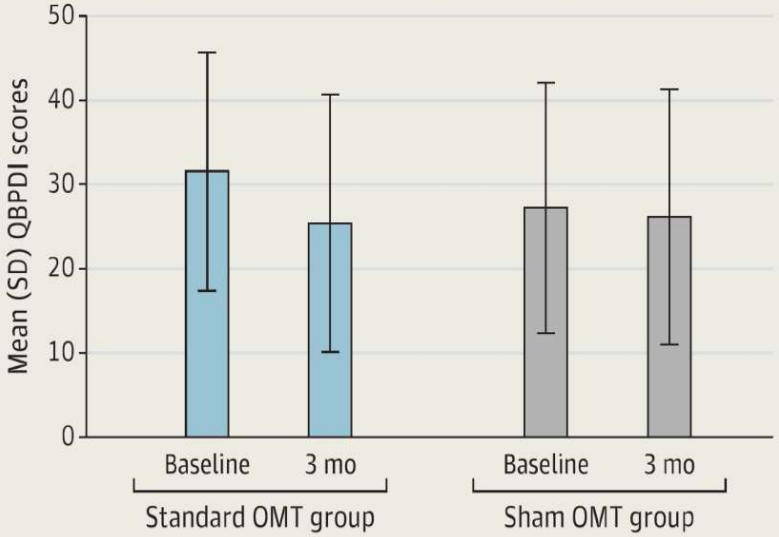
394 Participants analyzed

197 Standard osteopathic manipulative treatment (OMT)
6 sessions (1 every 2 wk) of standard OMT

197 Sham OMT
6 sessions (1 every 2 wk) of sham OMT

FINDINGS

At 3 mo, mean reduction in LBP-specific activity limitations via QBPDI score was statistically higher in the standard OMT group vs the sham OMT group; however, the clinical relevance of this effect is questionable



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SETTINGS / LOCATIONS

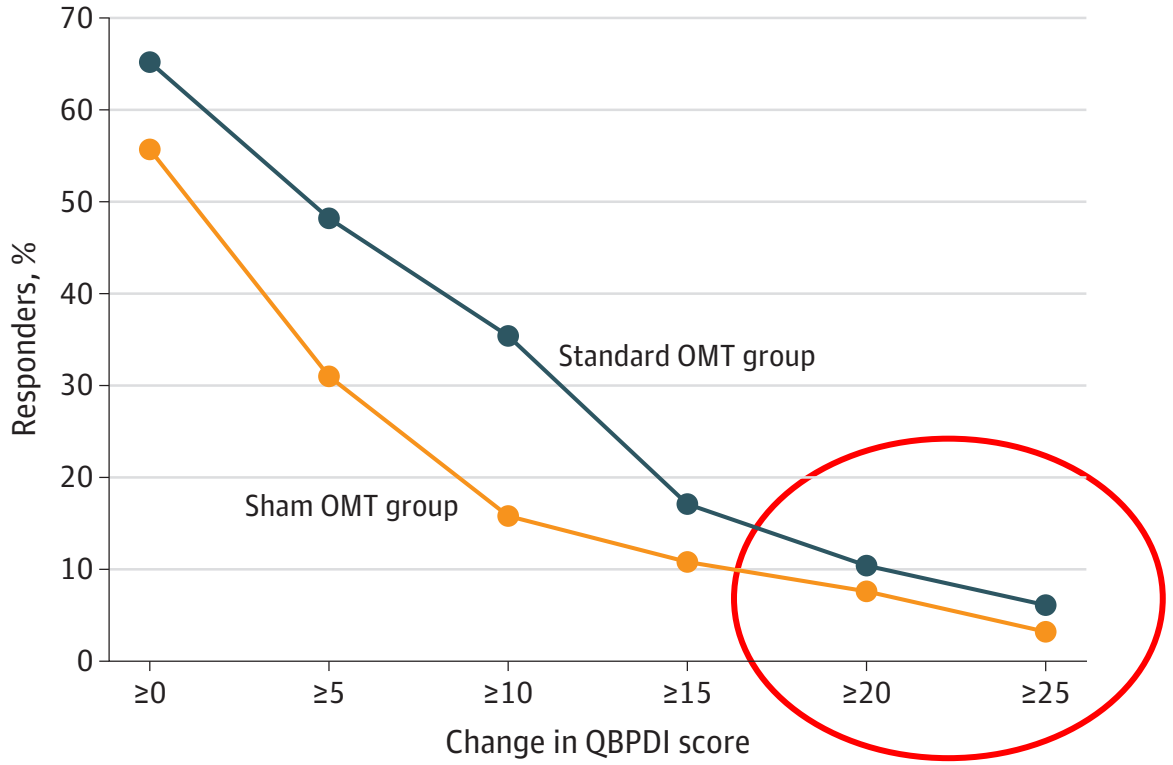
1 Tertiary care hospital in Paris, France

PRIMARY OUTCOME

Mean reduction in LBP-specific activity limitations at 3 mo via the self-administered Quebec Back Pain Disability Index (QBPDI), with scores ranging from 0 (no limitations) to 100 (maximum limitations)

Who are the super responders?

Figure 2. Cumulative Percentage of Responders' Analysis With Change in Quebec Back Pain Disability Index (QBPDI) Score at 3 Months



10,4%

7,6%

At 3 months, data were available for 164 participants in the standard osteopathic manipulative treatment (OMT) group and 159 in the sham OMT group.

Outline

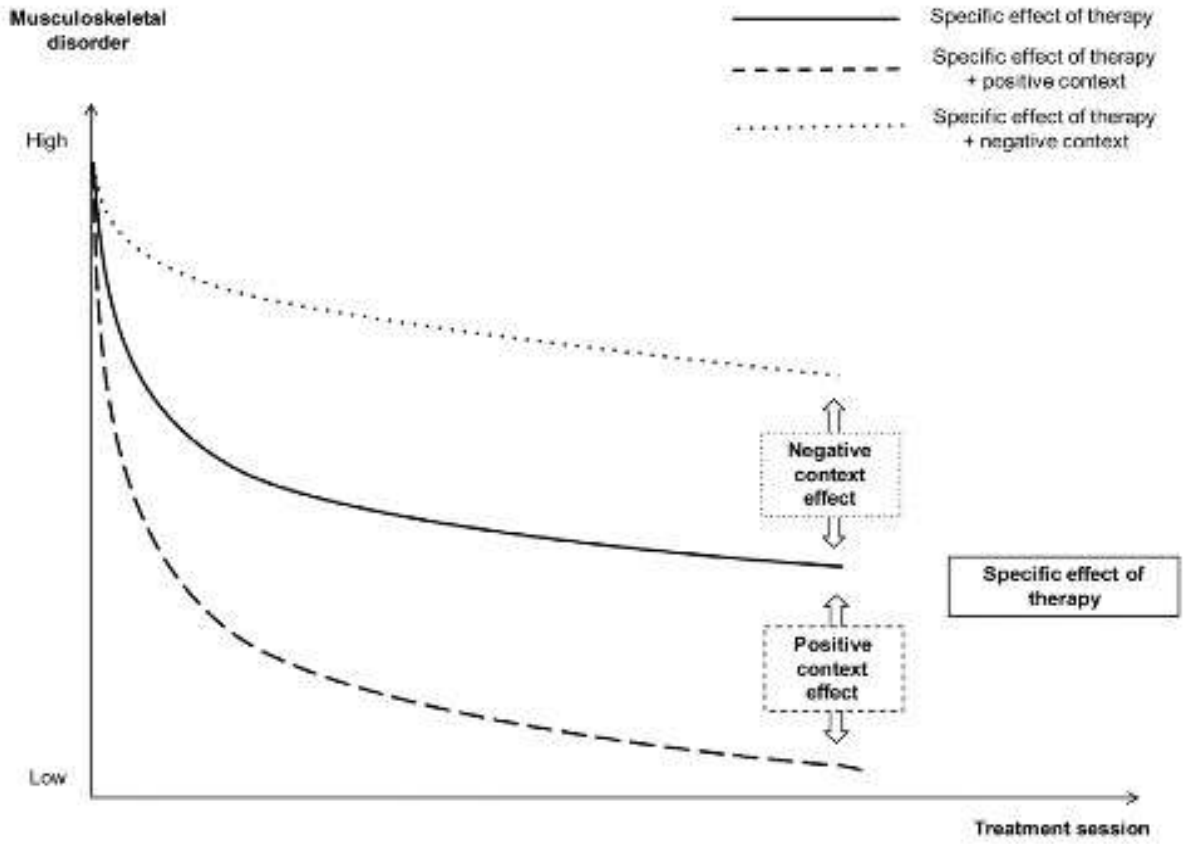
1. Osteopathic medicine & osteopathy
   1.1. French educational environment (French decrees, 2014)
   1.2. Osteopathic principles (1953 vs 2002)
2. Complex intervention methods to evaluate osteopathic care
3. LC-OSTEO: research question & design
4. LC-OSTEO: results & discussion
5. LC-OSTEO: possible perspectives
   5.1. Importance of contextual effects when applying OMT in osteopathic care
   5.2. Critical appraisal of traditional, body-centered models for osteopathic care
   5.3. Opportunity to develop evidence-informed, person-centered models for osteopathic care

How to handle cognitive dissonance in a professional environment?

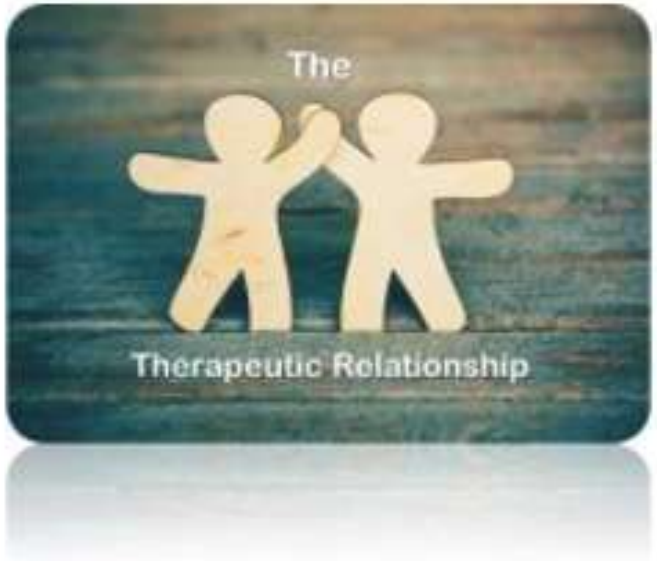
LC-OSTEO

- Effectiveness of osteopathic care not evaluated
- Contextual effects of osteopathic care controlled in both groups
- Specific effects of OMT within osteopathic care evaluated

Specific effects & contextual effects in manual therapy



(Testa and Rossettini, 2016)

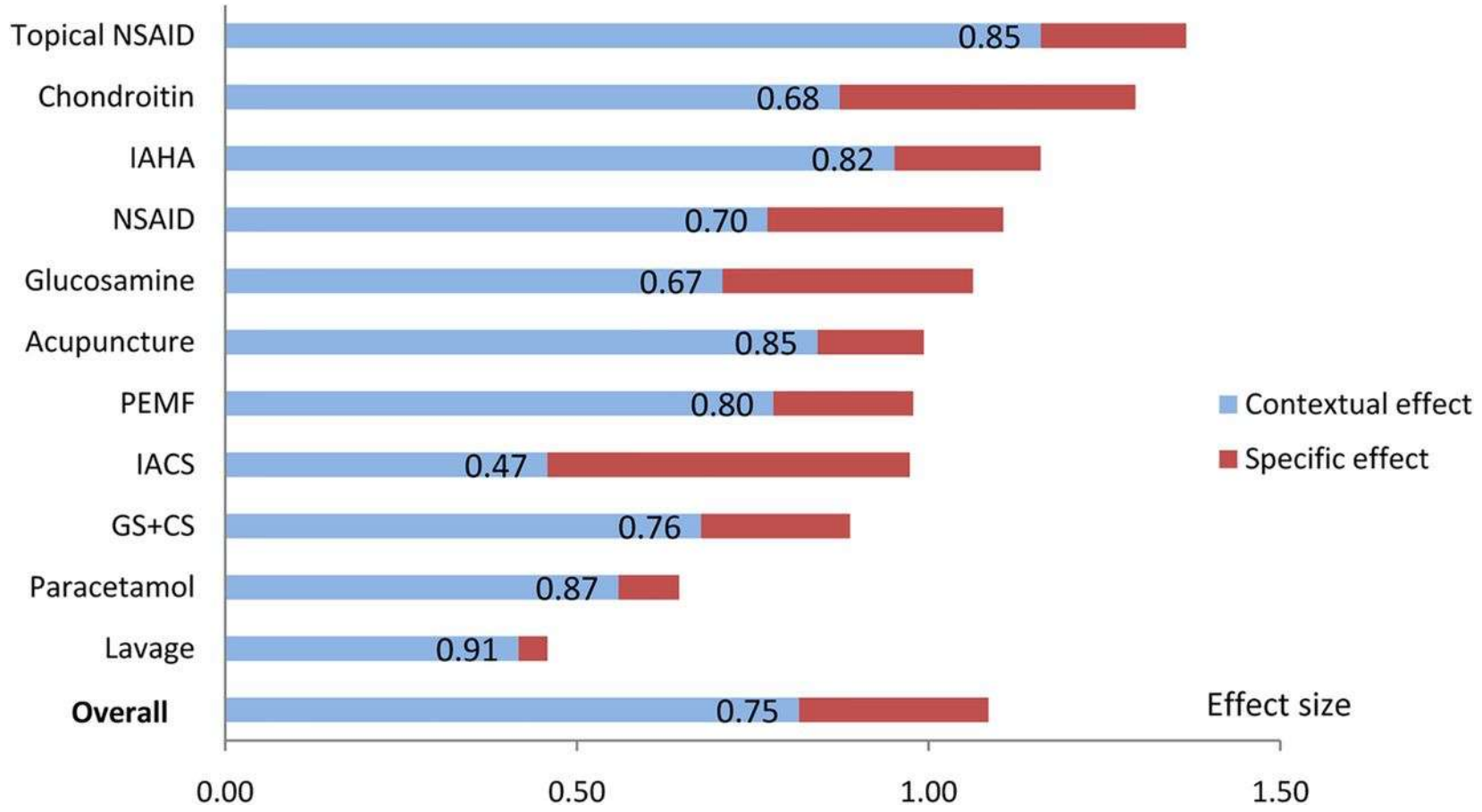


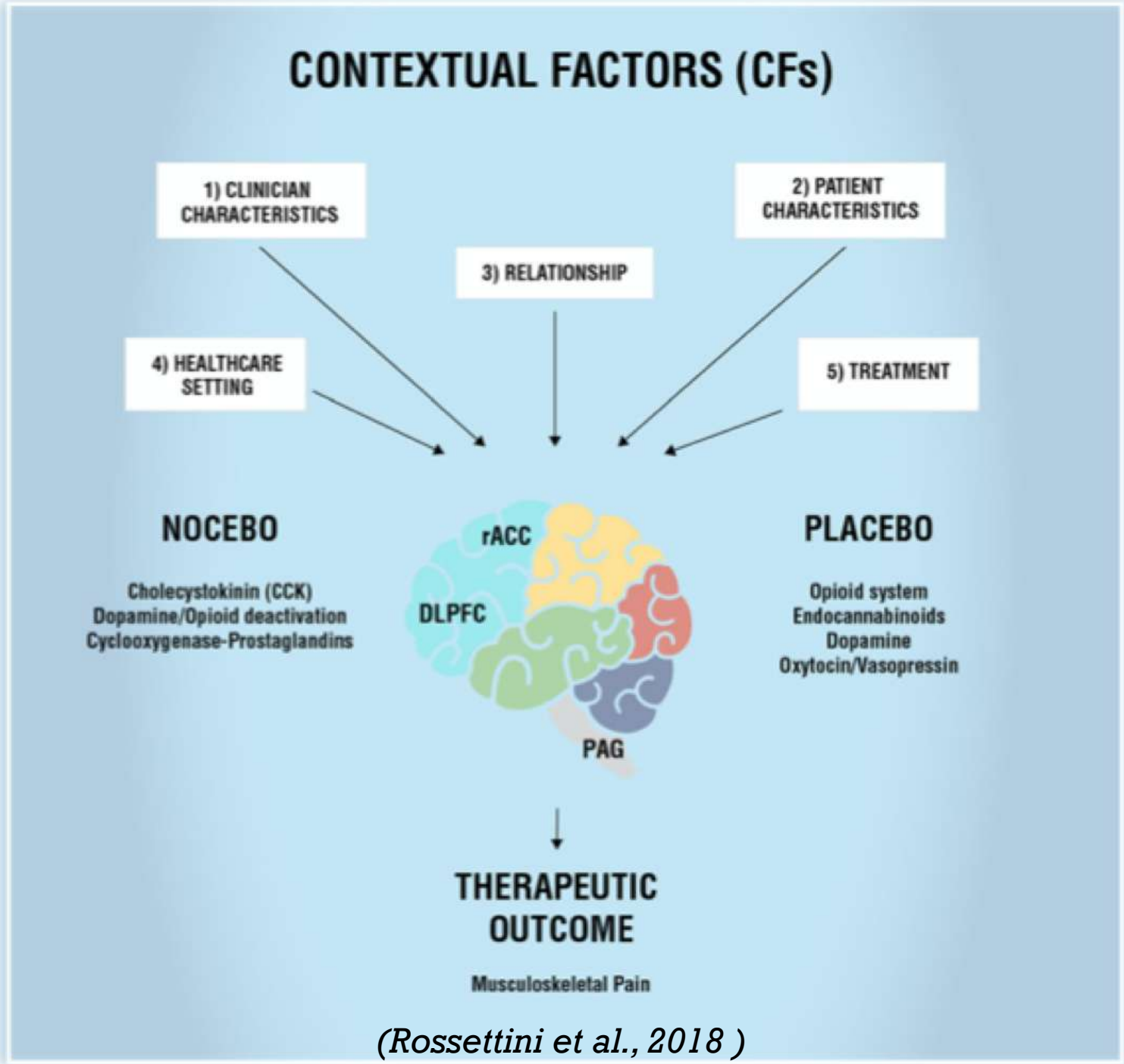
- 66% of variation for chronic pain
- 81% of variation for acute pain

(Menke, 2014)

Specific effects & contextual effects: pain in osteoarthritis

(Zou et al., 2016)





(Rossettini et al., 2018)

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Osteopathic care from a patient's perspective
(Consorti et al., 2020)

- A path of awareness that starts from an experience of pain
- Patients perceive and move their bodies differently
- OMT as one of many co-factors that initiates those changes

- Different conceptions of osteopathic care: what about practitioners?

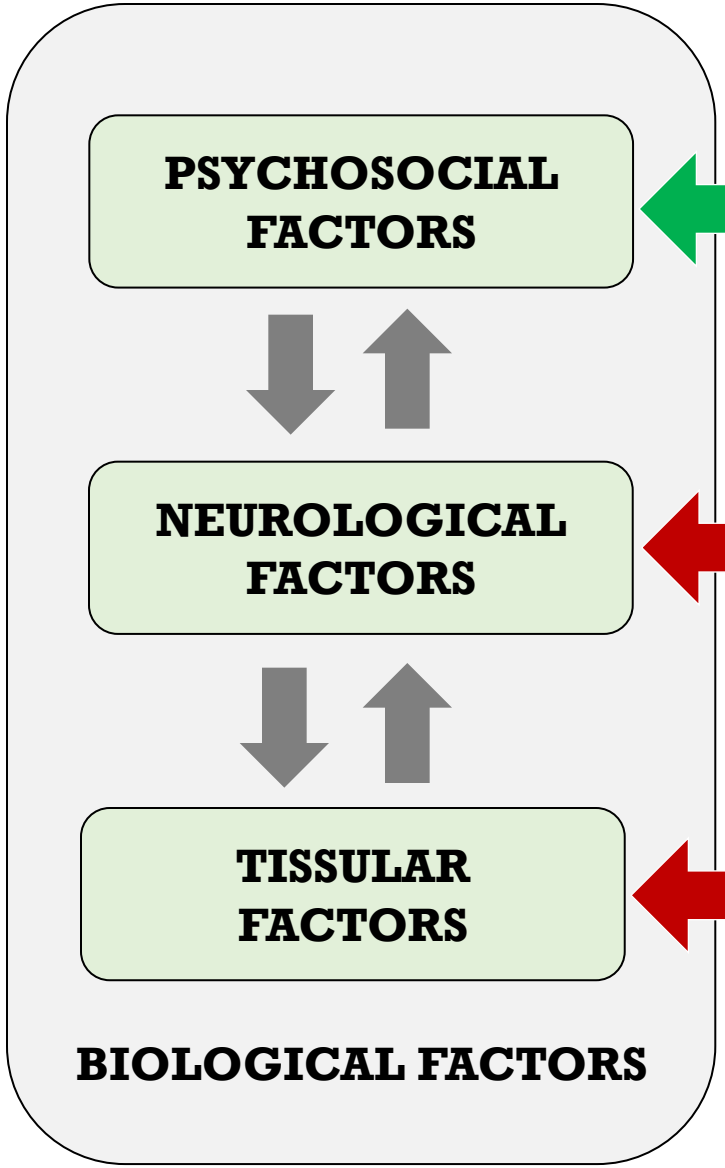
3 Different conceptions of osteopathic care

VIEW OF OSTEOPATHY	THERAPEUTIC APPROACH	INTERACTING WITH PATIENT & INTERPRETING CUES	APPROACH TO CLINICAL DECISION-MAKING & LEVEL OF PATIENT INVOLVEMENT	THERAPEUTIC GOAL
Practitioner-centred	Treater	Body	Practitioner-led (Low level)	Osteopath takes control & Responsability
Collaborative	Communicator	Person	Shared (Equal level)	Osteopath shares control & Guides patient
Empowerment	Educator	Patient	Patient-led (High level)	Osteopath facilitates learning and control with patient

(Adapted from Thomson et al., 2014; with permission)

3 Different conceptions of osteopatic care & osteopathic principles

(Adapted from Fryer, 2017, with permission)



PATIENT MANAGEMENT

OMT

OMT

Osteopath as a treater (1953 principles)

Osteopath as a communicator or a educator (2002 principles)

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Contents lists available at ScienceDirect

International Journal of Osteopathic Medicine

journal homepage: www.elsevier.com/locate/ijosm

Models and theoretical frameworks for osteopathic care – A critical view and call for updates and research

COME Collaboration Evidence Scale for guiding confidence in theoretical models used in care.

Level of evidence	Name	Criteria	Examples[a]	Expected practical attitude
A	Generalized theory	Theory resisted multiple temptations of falsification in different settings and with different populations. Consistent over time.	Person-centred theory, health hygiene theory, vaccine immunisation theory	Can be fully trusted without however excluding potential exceptions
B	Explanatory theory	Practical application tested and validated for specific populations or/and settings. Theory capable of explaining and predicting useful observed phenomenon.	Phenomenological models of the body, nutritional theory, cognitive behavioural theory, goal setting theory, transtheoretical model of change	Can be trusted in known explored settings at specific analytical levels
C	Model with empirical support	Testable relationships or construct confronted and supported by empirical observations. Findings support plausibility, consistency and construct of the model.	Neurophysiological mechanisms for spinal manipulation, neurovegetative allostatic model, motor energy-efficiency model, predictive processing theory, psychosocial determinants of health models, health literacy models	Can be used to explain some clinical or public health observations
D	Models with expert consensus alone	Consensus on construct with explicit explanation on causal relationships. Consistent, plausible and useful in providing guidance on the process of care.	"Five osteopathic models" approach	Can be used cautiously in practice in absence of a better model
E	Untested hypothetical model without broad consensus	Testable, plausible model with apparent internal consistency.	Osteopathic somatic dysfunction, the bioenergetic model, the motility model	Only rely on such models with much scepticism
F	Existing evidence against model	Internal incoherence, major inconsistencies with existing models of high level of evidence, or model repeatably contradicted by empirical observations.	Chiropractic subluxation model, Magoun's cranial model, homeopathic dilution theory, meridian traditional theory in acupuncture	Model not to be used as they are known to mislead and can generate mistrust

[a] Examples are for illustration purposes only and are not exhaustive. Level of evidence of each example is subject to changes depending of cumulated evidence.'

(Esteves et al., 2020)

Evidence-informed osteopathic care *(Fryer, 2017)*

International Journal of Osteopathic Medicine 25 (2017) 30–41

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International Journal of Osteopathic Medicine

journal homepage: www.elsevier.com/ijos

Masterclass

Integrating osteopathic approaches based on biopsychosocial therapeutic mechanisms. Part 1: The mechanisms

Gary Fryer, B.Sc.(Osteopathy), Ph.D. [a, b, *]

[a] College of Health and Biomedicine, Victoria University, Melbourne, Australia
[b] A.T. Still Research Institute, A.T. Still University, Kirksville, MO, USA

Role of OMT according to the 2002 osteopathic principles

- Patients expect OMT
- Specific effects associated with a nonspecific response
- Promoting sense-making with an individualized narration for physical symptom experience

Osteopathic care

- Reassurance to reduce fear & anxiety
- Address inappropriate beliefs & behaviors
- Pain education
- Promote confidence in movement
- Encourage increased activity

Osteopathic professional identity challenged: science or pseudoscience?

- **Orthopaedic Manual Physical Therapy (OMPT)?**
- a specialised area of physiotherapy / physical therapy for the management of neuro-musculoskeletal conditions, based on clinical reasoning, using highly specific treatment approaches including manual techniques and therapeutic exercises.
- encompasses, and is driven by, the available scientific and clinical evidence and the biopsychosocial framework of each individual patient.

World Physiotherapy SUBGROUP

- **Contemporary osteopathic care?**

The legacy and implications of the body-mind-spirit osteopathic tenet: a discussion paper evaluating its clinical relevance in contemporary osteopathic care	Sep 04, 2020	May 26, 2021	Accept

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- Edition of the manuscript: Laura Smales and Jacqueline Lamb
- Edition of the PowerPoint presentation: Deborah Goggin

- Participants' recruitment: Dr. Marie Fechtenbaum, Dr. Clémence Palazzo, Dr. Guillaume Paris and the internes du Service de Rééducation et de Réadaptation de l'Appareil Locomoteur et des Pathologies du Rachis, Hôpital Cochin, Paris

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In memoriam

- **Prof. Serge Poiraudeau** (1960-2017) supported the idea, wrote the original protocol, obtained funding, and was the principal investigator of the trial. He closely supervised the project until his duties were taken over by Prof. Rannou.

- In accordance with journal policies, because he could not meet 2 of the 4 International Committee of Medical Journal Editors authorship criteria (i.e., final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved), Prof. Poiraudeau could not be listed as an author and was removed at submission.

- We would like to acknowledge his huge contribution to this work and honor his memory as an incredible researcher and colleague, a thoughtful mentor, and a close friend.

Thanks for your attention

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