CENTER FOR OSTEOPATHIC MEDICINE COLLABORATION

The Foundation COME Collaboration ONLUS

Research Report – 2016

Table of contents

Introduction

The following report presents the most relevant publications, papers, articles and book chapter issued on several medical and scientific journals (at national and international level) as well as published on books and websites on 2016. Papers were written and published by COME Collaboration's members, doing research for and collaborating with the Foundation.

For more information: info@comecollaboration.org
Visit also: www.comecollaboration.org

1. ***"State of affairs of osteopathy in the Benelux: Benelux Osteosurvey 2013"*** - **Patrick L.S.van Dun, Mioara Alina Nicolaie, Arnout Van Messem.** International Journal of Osteopathic Medicine (2016) 20, 3e17

The Commission for Osteopathic Research, Practice and Promotion (CORPP) and the *Stichting Wetenschappelijk Osteopathisch Onderzoek (SWOO)* identified the need to gather data about the practice profile of osteopaths in Belgium, the Netherlands and Luxembourg (together called the Benelux), to obtain actual figures regarding the profession to guide strategic planning concerning its promotion and future research projects.

All Benelux osteopaths who could be contacted (n = 2,050) were invited to complete an online questionnaire survey between December 20, 2012 and March 26, 2013. Descriptive and inferential statistics were used to analyse the data; specific research questions were tested using linear regression and proportional odds models. Results from previous national and international surveys of specific groups in the osteopathic profession were used for comparative analysis.

The response rate was 52.15% (n = 1,069). Almost one third of the respondents were female. The mean time since graduation was 11 years. The vast majority of respondents were self-employed and in private practice (91.94%, n = 935); one third worked in a group practice (33.82%, n = 344). They consult an average of 9 patients a day (37.7 patients a week) and the majority spend between 46 and 60 min with a new patient (50.51%, n = 498) and between 30 and 45 min with a returning patient (64.20%, n = 633). Practice working hours are on average 29.7 per week. The most commonly used diagnostic techniques are: inspection, palpation of position/structure and of movement. Only 2.43% (n = 24) of the respondents do not make a diagnosis with every consultation and the vast majority formulate a differential diagnosis before deciding to treat a patient (90.06%, n. 888).

The most commonly used treatment techniques are: visceral manipulation, neuro and viscerocranial techniques and general osteopathic mobilisations. Most common complaints by body region estimated by the respondents were the lumbar spine, cervical spine and pelvis. Respondents also estimated that patients were mostly self-referred.
The results provide a benchmark for some aspects of osteopathic service delivery, which may
inform potential purchasers of healthcare services; they also provide a baseline for estimating growth and scope of practice in the Benelux. Further research is required to enhance the validity of information about reported patients.

Table 2 Practice characteristics for the different Benelux regions.

Region	Benelux ($n = 1069$)		Flanders ($n = 400$)		French community ($n = 302$)		Netherlands ($n = 347$)		Luxemburg ($n = 20$)	
Characteristics	Amount	Number (%) of respondents	Amount	Number (%) of respondents	Amount	Number (%) of respondents	Amount	Number (%) of respondents	Amount	Number (%) of respondents
Consultation fee new patient	58.69*	972 (90.92)	46.38*	360 (90.00)	50.66*	275 (91.06)	78.88*	337 (97.12)	58.15*	17 (85.00)
Consultation fee returning patient	55.80*	972 (90.92)	44.98*	360 (90.00)	48.91*	275 (91.06)	71.98*	337 (97.12)	55.80*	17 (85.00)
Consultation length new patient (min)	<30	14 (1.42)	<30	7 (1.92)	<30	4 (1.42)	<30	3 (0,89)	<30	0 (0.00)
	30–45	415 (42.09)	30–45	197 (53.97)	30–45	135 (47.87)	30–45	83 (24.48)	30–45	5 (29.41)
	46–60	498 (50.51)	46–60	151 (41,37)	46–60	134 (47,52)	46–60	213 (62,83)	46–60	11 (64.71)
	>60	59 (5.98)	>60	10 (2.74)	>60	9 (3.19)	>60	40 (11.80)	>60	1 (5.88)
Consultation length returning patient (min)	<30	51 (5.17)	<30	23 (6.30)	<30	21 (7.45)	<30	7 (2.06)	<30	0 (0.00)
	30–45	633 (64.20)	30–45	272 (74.52)	30–45	193 (68.44)	30–45	168 (49.56)	30–45	9 (52.94)
	46–60	284 (28.80)	46–60	70 (19.18)	46–60	64 (22.70)	46–60	150 (44.25)	46–60	8 (47.06)
	>60	18 (1.83)	>60	0 (0.00)	>60	4 (1.42)	>60	14 (4.13)	>60	0 (0.00)
Consults/day	9* (8)	929 (86.90)	9.7* (8)	339 (84.75)	7.4* (7)	259 (85.76)	9.3* (9)	331 (95.39)	8.2* (7)	17 (85.00)
Consults/week	37.7* (35)	929 (86.90)	41.7* (35)	339 (84.75)	32.6* (30)	259 (85.76)	37.4* (36)	331 (95.39)	35.9* (35)	17 (85.00)
Hours practice/ week	29.7*	1017 (95.14)	30.0*	376 (94.00)	25.3*	293 (97.02)	32.7*	345 (99.42)	29.6*	17 (85.00)
Group practice	344 (33.82)°	1017 (95.14)	125 (33.24)°	376 (94.00)	96 (32.43)°	296 (98.01)	123 (35.65)°	345 (99.42)	11 (64.71)°	17 (85.00)

* = mean (median for categorical variables); ° = number (%) of respondents working in a group practice.

Table 6 The 10 most common specific complaints for which a Benelux osteopath is consulted; in descending order of mean values on a scale from 0 (never) to 4 (always) (mean not shown).

Specific complaints	0	1	2	3	4	M
Neck complaints	3 (0.32)	5 (0.54)	121 (13.02)	750 (80.73)	50 (5.38)	3
Lumbago	2 (0.22)	9 (0.97)	140 (15.12)	714 (77.11)	61 (6.59)	3
Headache and migraine	4 (0.43)	14 (1.51)	248 (26.72)	633 (68.21)	29 (3.13)	3
Cervicobrachialgia	9 (0.97)	39 (4.20)	324 (34.88)	535 (57.59)	22 (2.37)	3
Sciatica	15 (1.62)	79 (8.51)	297 (32.00)	507 (54.63)	30 (3.23)	3
Stress related complaints	19 (2.06)	75 (8.12)	326 (35.28)	472 (51.08)	32 (3.46)	3
Digestive disorders	22 (2.37)	100 (10.78)	405 (43.64)	385 (41.49)	16 (1.72)	2
Complaints during/ after pregnancy/ childbirth	17 (1.83)	137 (14.75)	446 (48.01)	315 (33.91)	14 (1.51)	2
Baby colic	88 (9.48)	110 (11.85)	323 (34.81)	385 (41.49)	22 (2.37)	2
Irritable bowel syndrome	36 (3.88)	161 (17.37)	395 (42.61)	325 (35.06)	10 (1.08)	2

Number of respondents; percentages are given between brackets; M = Median.

2. ***"The biomechanical model in manual therapy: Is there an ongoing crisis or just the need to revise the underlying concept and application?"*** **- Christian Lunghi, Paolo Tozzi, Gianpiero Fusco.** J Bodyw Mov Ther. (2016) 20(4):784-799.

Different approaches to body biomechanics are based on the classical concept of "ideal posture" which is regarded as the state where body mass is distributed in such a way that ligamentous tensions neutralize the force of gravity and muscles retain their normal tone, as result of the integration of somatic components related to posture and balance mechanisms. When compromised, optimal posture can be restored through the balanced and effective use of musculoskeletal components; however, various research findings and the opinion of experts in this field suggest a move away from the dogmas that have characterized the idea of health dependent on ideal posture, to promote instead dynamic approaches based on the interdependency of the body systems as well as on the full participation of the person in the healing process. Following these concepts, this article proposes a revised biomechanical model that sees posture as the temporary result of the individual's current ability to adapt to the existing allostatic load through the dynamic interaction of extero-proprio-interoceptive information integrated at a neuromyofascial level. Treatments using this revised model aim to restore the optimal posture available to the person in that particular given moment, through the efficient and balanced use of neuro-myofascia-skeletal components in order to normalize aberrant postural responses, to promote interoceptive and proprioceptive integration and to optimize individual responses to the existing allostatic load. The latter is achieved via multimodal programs of intervention, in a salutogenic approach that, from a traditional perspective, evolves on an anthropological basis, to the point of centering its work on the person.

Figure 1 **The fasciagenic model of somatic dysfunction** (Tozzi, 2015b): the diagram shows two main interacting fascial changes – structural and functional – that may underlie somatic dysfunction and account for its palpable features (tissue texture changes, asymmetry, restriction of motion, tenderness). They may occur through various types of interactions and under different kinds of influences. Several dysfunctional events may produce different forms of forces and responses in the fascia with consequent dysfunctional processes.

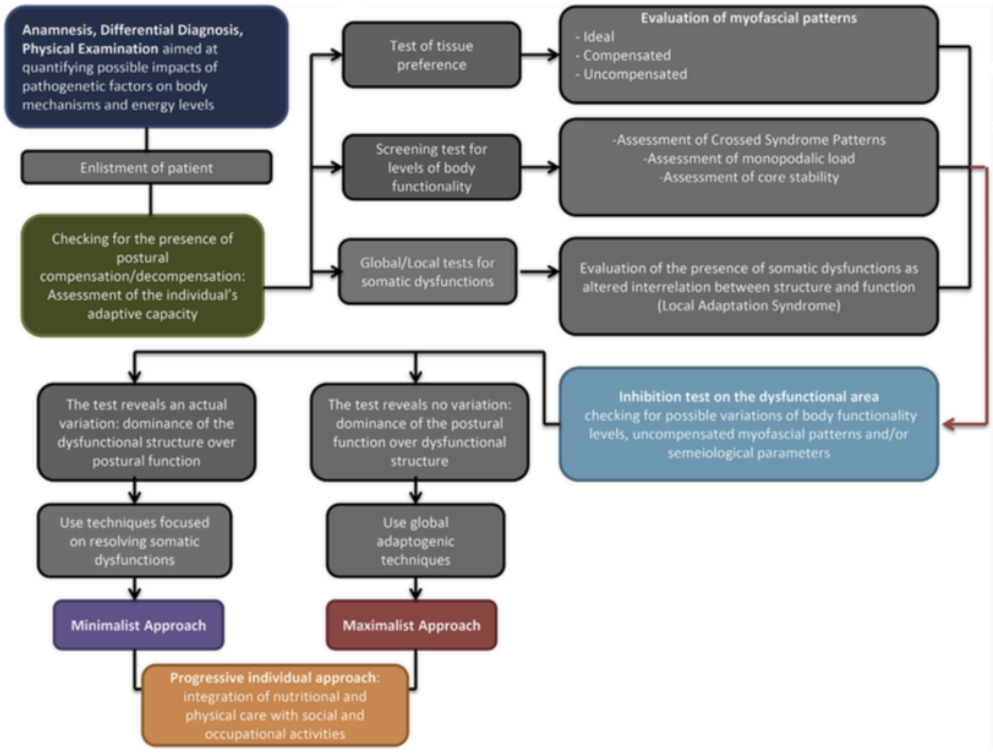


Figure 2 **Evaluation and clinical decision processes of the revised biomechanical model:** the operator finalizes a clear picture of the global and biomechanical postural condition of the patient through the application of a process of evaluation and selection of the most appropriate therapeutic approach.

3. ***"Using the template for intervention description and replication (TIDieR) as a tool for improving the design and reporting of manual therapy interventions"*** **- Gerard Alvarez, Francesco Cerritelli, Gerard Urrutia.** Man Ther. 2016 Mar 11. pii: S1356-689X(16)00033-3.

The detailed reporting of any research intervention in clinical trials is crucial to evaluate the applicability of the findings into a routinely practice-based context (external validity). Over the past decade, biased under-reporting and over-reporting of research has increasingly been acknowledged as unacceptable on both scientific and ethical grounds. It has been estimated that, in any medical field, as much as 60% of the published literature reported incomplete intervention details. This problem, common for all types of treatments and interventions, is significantly worse for non-pharmacological trials. Among the various initiatives that have been undertaken to improve the intervention description, the Template for Intervention Description and Replication (TIDieR) has to be highlighted as the most promising.

MATERIAL/METHODS. A narrative reflection has been made by the authors on the importance of an accurate and detailed reporting of manual interventions in order to increase its applicability and reproducibility. A list of particular and relevant issues involved in the delivery of manual therapies is presented and how the TIDieR checklist addresses all of this aspects.

RESULTS. Improvements in the general reporting of manual interventions could have several implications. As possible effects, it would lead to: a) the possibility to explore and discuss underpinning mechanisms of actions still unexplained; b) provide insights into processes that are inaccessible using current experimental techniques; c) validate predictions against experimental data, which is of utmost importance from a scientific perspective; d) suggest adaptations of health care systems to the evolution of scientific and clinical manual medicine, which can be considered an ultimate long term outcome and e) facilitate more accurate assessment in terms of cost-effectiveness and cost-utility in the implementation of these disciplines.

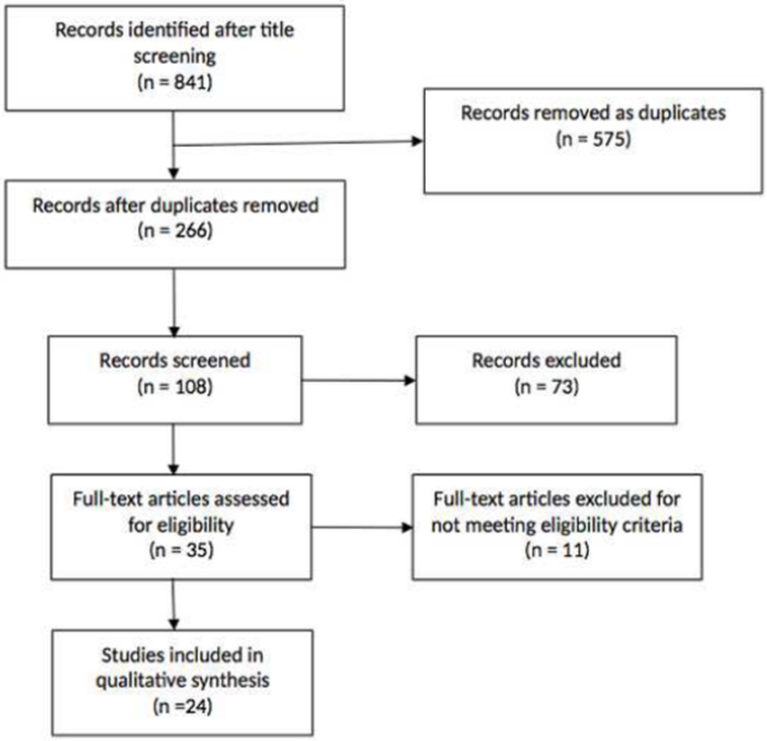
CONCLUSIONS. In general, TIDieR offers both researchers and clinicians a helpful and comprehensive guidance on how MT interventions have to be designed and reported taking into account the clinical complexity of MTs and the need to satisfy research gold standards. Following the TIDieR checklist would increase the probability of studies being replicated and reproduced, extending the external validity of results and yielding, potentially, the generalizability of benefits. Moreover, it can contribute to several other positive changes such as: 1) increased awareness of what is regarded as a complete description of intervention by authors and reviewers as well as by journals and editors; 2) better understanding of manual practice for external professionals, unfamiliar with the given manual medicines; 3) enhancing the scientific credibility of MTs; 4) increasing the likelihood of creating profitable cross-disciplinary and inter-disciplinary discussions; 5) defining clearer competencies, magnifying strengths or limitations to patients and for policymakers.

4. ***"Osteopathic manipulative treatment in gynecology and obstetrics: a systematic review"*** – **Nuria Ruffini, Giandomenico D'Alessandro, Lucia Cardinali, Franco Frondaroli, Cerritelli F.** Complement Ther Med. 26 (2016) 72–78

Virtually every woman is affected by a gynecological condition at some point of her life 1, throughout the fertile period or in the post-menopausal age. CAMs 2, osteopathy among them 3, offer diverse approaches to help female patients in dealing with such problems, although their effectiveness has been poorly explored in terms of clinical evidence. Hence the necessity of a systematic review relating osteopathic medicine and gynecological conditions as a whole. Primary outcome was to summarize the evidence on the effectiveness of OMT versus any other type of control procedures in patients with gynecologic and obstetric disorders; the secondary outcomes focused on the quantity and quality of the information concerning side effects after osteopathic treatments in said patients.
Every type of study design was included, the eligible interventions were osteopathic treatment or techniques, without restrictions of approach and type of control; the population included women after menarche in all gynecologic and obstetric conditions. The methodology followed the Cochrane guidelines for systematic reviews and meta-analyses, and the tools used for the evaluation of the included RCTs were The Cochrane Collaboration's Risk of Bias (RoB) Assessment tool 4 and the GRADE. No tools were identified to critically and systematically assess non-RCT studies 5.

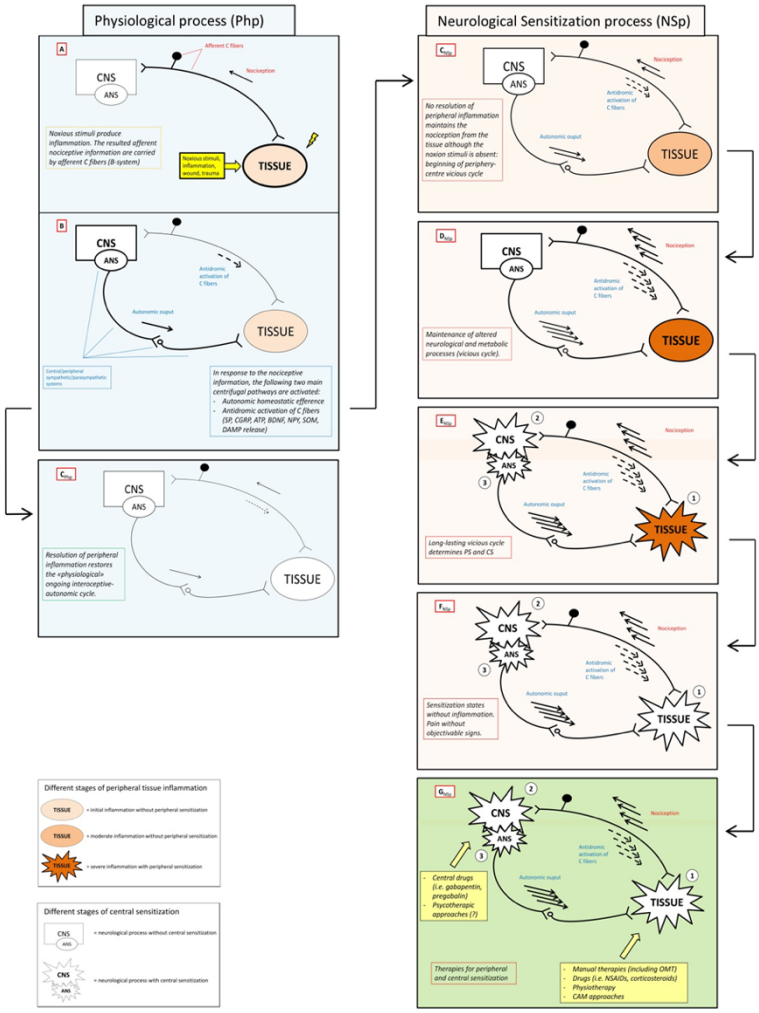
After the initial screening, 24 papers enrolling a total of 1840 subjects were included in the systematic review (Fig. 1). Study outcomes considered back pain and low back function in pregnancy 3, 6, 7, 8, 9-11, hemodynamic control during pregnancy 12, pain and drug use during labor 13, 14, 15, 16, conception rates in infertility and subfertility 17, 18, 19, 20, pain in dysmenorrhea 21, 22, 23, typical symptoms of perimenopause and menopause 24, 25-27, and pelvic pain 28. Both direct and indirect osteopathic techniques were performed, integrated in protocolled sequences or in a patients' need-based treatments. 50% of studies included a control group, procedures being sham therapy, placebo, no intervention, and usual care. Only 8/24 trials were RCTs, their GRADE ranked from low 11, 23, 27 to moderate 7, 13, high 6, 21 and unclear 12.
Despite positive trends can be easily identifiable through the different clinical outcomes,
the diversity of study designs and outcomes resulted in a significant heterogeneity; precluding the performing of a meta-analysis and the attainment of robust conclusions on the effect of OMT in gynecologic and obstetric conditions.
Within these limits, it can be pointed out that the main strength of the current study is its originality, which allows for a better understanding of what is already known about the effectiveness of osteopathy in gynecological/obstetrics disorders, suggests clinical 'food for thoughts', but also highlights the need for future and more rigorous research.

Fig. 1


Records identified after title screening (n = 841)
Records removed as duplicates (n = 575)
Records after duplicates removed (n = 266)
Records screened (n = 108)
Records excluded (n = 73)
Full-text articles assessed for eligibility (n = 35)
Full-text articles excluded for not meeting eligibility criteria (n = 11)
Studies included in qualitative synthesis (n =24)

5. **"Sensitization and Interoception as Key Neurological Concepts in Osteopathy and Other Manual Medicines" - Giandomenico D'Alessandro, Francesco Cerritelli, Pietro Cortelli.** Front Neurosci. 2016 Mar 10;10:100. doi: 10.3389/fnins.2016.00100. eCollection 2016

This qualitative review starts from the need to include in the manual medicines' field, especially osteopathy, the new neuroscientific concepts of sensitization and interoception enriching the well-known exteroceptive knowledge used in the clinical setting.



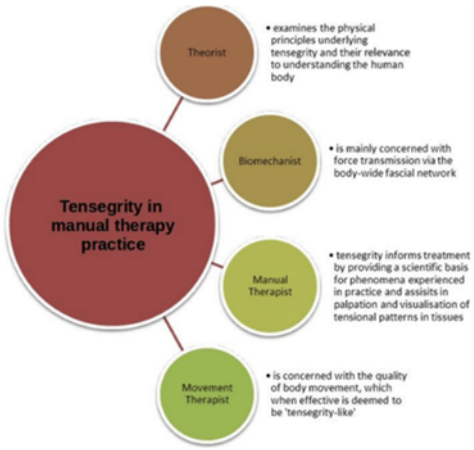
The paper firstly explain why it is so important introducing this new paradigm; secondly it explores the two concepts according to the latest acquisitions in the neuroscientific field; thirdly it introduces the so-called interoceptive paradigm in which the afferent interoceptive information about the metabolic condition of the body becomes central because it is able to trigger and/or maintain sensitization states in the CNS. The autonomic nervous system and the neurogenic inflammation become the essential outcomes to be investigated considering their close onthogenetic and functional links with the interoceptive source.

Finally the authors review the updated literature about the 'interoceptive-trophism', 'autonomic-trophism' and anti-inflammatory role of osteopathic medicine.

6. ***"Tensegrity and manual therapy practice: a qualitative study"*** **- David J. Hohenschurz-Schmidt, Jorge E. Esteves, Oliver P. Thomson.** International Journal of Osteopathic Medicine (2016) 21, 5e18

Tensegrity has been proposed as a unifying mechanism between structures at cellular, connective tissue and whole body level. Originating in the fields of sculpture and architecture, tensegrity has recently received increasing attention from practitioners and researchers of manual therapy. Despite this, evidence regarding the role of the tensegrity principle to manual therapy practice is scarce. To this end, we explored experienced manual therapists' understanding of tensegrity, as a means of investigating whether the knowledge of tensegrity can inform manual therapy practice. We looked particularly at the following research questions: Where does that interest in tensegrity come from? Does it change the way therapists work, how they perceive the human body or make clinical decisions, and if so how? For this study, eight semi-structured interviews were conducted with experts from manual therapy, fascia research and/or manual therapy education fields, and analysed using grounded theory methods. We found that participants' general definition of tensegrity concurred with Ingber (1998) i.e., tensegrity structures consist of isolated compression elements connected through a continuous network of tensile elements. Our findings indicate that tensegrity may inform clinical decision-making in manual therapy. A theory has been constructed that may help to explain aspects of manual therapy practitioners approaches to tensegrity. In the diagrammatic representation of our explanatory model depicted in Fig 1, each category refers to a conceptual approach to the tensegrity model in manual therapy practice. They include interviewees' underlying perceptions and opinions and were interpreted descriptively as four types of tensegrity-practitioners.

Our research has implications for practice. It can be argued that tensegrity may be useful to the practice of manual therapy, and it may serve as a theoretical underpinning of previously conceived clinical models and subjective clinical experience (palpation). Moreover, tensegrity may also inform decision-making processes by providing a biomechanical model of the human body.



7. ***"The paradox of sham therapy and placebo effect in osteopathy: A systematic review"*** - **Francesco Cerritelli, Marco Verzella, Luca Cicchitti, Giandomenico D'Alessandro, Nicola Vanacore.** Medicine (2016) 95:35(e4728)

Background: Placebo, defined as "false treatment," is a common gold-standard method to assess the validity of a therapy in both pharmacological trials and manual medicine research where placebo is also referred to as "sham therapy." In the medical literature, guidelines have been proposed on how to conduct robust placebo-controlled trials, but mainly in a drug-based scenario. In contrast, there are not precise guidelines on how to conduct a placebo-controlled in manual medicine trials (particularly osteopathy). The aim of the present systematic review was to report how and what type of sham methods, dosage, operator characteristics, and patient types were used in osteopathic clinical trials and, eventually, assess sham clinical effectiveness.

Methods: A systematic Cochrane-based review was conducted by analyzing the osteopathic trials that used both manual and nonmanual placebo control. Searches were conducted on 8 databases from journal inception to December 2015 using a pragmatic literature search approach. Two independent reviewers conducted the study selection and data extraction for each study. The risk of bias was evaluated according to the Cochrane methods.

Results: A total of 64 studies were eligible for analysis collecting a total of 5024 participants. More than half (43 studies) used a manual placebo; 9 studies used a nonmanual placebo; and 12 studies used both manual and nonmanual placebo (Table 1). Data showed lack of reporting sham therapy information across studies. Risk of bias analysis demonstrated a high risk of bias for allocation, blinding of personnel and participants, selective, and other bias. To explore the clinical effects of sham therapies used, a quantitative analysis was planned. However, due to the high heterogeneity of sham approaches used (Table 2) no further analyses were performed.

Conclusion: High heterogeneity regarding placebo used between studies, lack of reporting information on placebo methods and within-study variability between sham and real treatment procedures suggest prudence in reading and interpreting study findings in manual osteopathic randomized controlled trials (RCTs). Efforts must be made to promote guidelines to design the most reliable placebo for manual RCTs as a means of increasing the internal validity and improve external validity of findings.

Table 1

Characteristics of the sham groups, divided into the manual, nonmanual, and combined (manual and nonmanual).

	N	n (%)	Mean	SD	Range
Manual			—	—	—
Jadad score (0–5)	43	43 (100)	3†	—	0–5
RCT study design	43	39 (91)	—	—	—
Sample size	43	43 (100)	70	110	10–710
Female	43	38 (88)	36	52	8–333
Age, y	43	33 (77)	38	23	0–83
Healthy subjects	43	10 (23)	—	—	—
Withdrew in general	43	42 (98)	2	5	0–25
Year of publication	43	43 (100)	2009	5	1994–2015
Nonmanual					
Jadad score (0–5)	9	9 (100)	3†	—	1–4
RCT study design	9	8 (89)	—	—	—
Sample size	9	9 (100)	81	48	16–146
Female	9	9 (100)	62	39	16–145
Age, y	9	8 (89)	35	10	23–53
Healthy subjects	9	1 (11)	—	—	—
Withdrew in general	9	9 (100)	2	3	0–10
Year of publication	9	9 (100)	2007	8.8	1985–2014
Combined (manual + nonmanual)					
Jadad score (0–5)	12	12 (100)	4†	—	0–5
RCT study design	12	8 (67)	—	—	—
Sample size	12	12 (100)	108	153	10–455
Female	12	12 (100)	75	129	0–400
Age, y	12	11 (92)	41	20	24–87
Healthy subjects	12	4 (33)	—	—	—
Withdrew in general	12	12 (100)	34	89	0–311
Year of publication	12	12 (100)	2011	4	2003–2015

N = total number of studies that fall in the category; n (%) = total number (and percentage) of research that reported that given parameter.
† Median.

Table 2

Different characteristics of sham scenario in manual, nonmanual, and combined groups.

	Manual			Nonmanual			Combined		
	n	N	% (95% CI)	n	N	% (95% CI)	n	N	% (95% CI)
Type of touch	25	43		—	—	—	10	12	
Light	10	25	40 (22–61)	—	—	—	9	10	90 (44–96)
Gentle	9	25	36 (19–57)	—	—	—	—	—	—
Soft	4	25	16 (5–37)	—	—	—	—	—	—
Hard	0	25	—	—	—	—	1	10	10 (0–46)
Therapeutic	1	25	4 (0–22)	—	—	—	—	—	—
Type of touchless procedure	—	—	—	9	9		11	12	
Magnet therapy	—	—	—	1	9	11 (0–49)	—	—	—
Ultrasound	—	—	—	4	9	44 (15–77)	2	11	18 (3–52)
Laser	—	—	—	1	9	11 (0–49)	—	—	—
Diathermy	—	—	—	1	9	11 (0–49)	—	—	—
Usual care	—	—	—	—	—	—	6	11	55 (25–82)
Placebo NSAID	—	—	—	1	9	11 (0–49)	—	—	—
No intervention	—	—	—	2	9	22 (4–60)	4	11	36 (12–68)
Type of practitioner	27	43		5	9		5	12	
Osteopath	11	27	41 (23–61)	2	5	40 (7–83)	3	5	60 (17–93)
Physician	5	27	19 (7–39)	2	5	40 (7–83)	2	5	40 (7–83)
Osteopathic physician	4	27	15 (5–35)	—	—	—	—	—	—
Physical therapist	3	27	14 (4–36)	—	—	—	—	—	—
Others	2	27	7 (1–26)	1	5	20 (0–70)	—	—	—
Practitioners' years of experience	6	43	14 (6–29)	0	9	—	1	12	8 (0–40)
Training for practitioners	1	43	2 (0–14)	1	9	11 (0–49)	3	12	25 (7–57)

Type of touch intends to report the different touch-based manual approaches described in the studies. The subcategories are relative to the classification of the typology of touch that was used in the different research. n = total number of research that reported that given parameter. N = total number of studies that fall in the category. Description of touch was particularly diverse across trials. Light touch, for example, was described as placing hands on bodily parts or applying light pressure on specific body region. Gentle touch was referred, for example, as placing hands on body districts and gently moving them.

8. ***"Osteopathic manipulative treatment in neurological diseases: Systematic review of the literature"*** **– Francesco Cerritelli, Nuria Ruffini, Eleonora Lacorte, Nicola Vanacore.** J Neurol Sci. 2016 Oct 15;369:333-41

As neurological disorders largely affect the global population1, the international community is committed to the improvement of prevention strategies, treatments and the management of neurological patients. Multidisciplinary approaches are also suggested as potentially effective, and an increasing number of patients asks for complementary and alternative medicine as a support to usual care2. Despite the popularity of the approach in the clinical context, few clinical trials were carried out investigating the effect of osteopathy on neurological patients, and none of them reported robust evidence supporting its use. Moreover, no systematic reviews have been published; thus, the decision of performing the present systematic review. The primary outcome was to estimate the efficacy and/or effectiveness of OMT compared with any other type of alternative treatment in patients with neurological disorders. The safety of osteopathic treatment as well as the number and type of reported side effects were considered as secondary outcomes.

The present systematic review included multi-center, single-center, quasi-randomized and randomized clinical controlled trials, interrupted time series, controlled clinical trials, and observational studies. The considered population included patients from any socio-demographic condition, of both genders and any age class, that reported a neurological condition. Only studies considering OMT as the main intervention of interest were included.

All included trials were assessed using to the Cochrane risk of bias (RoB) tool3 and the Jadad score4, other types of studies were assessed using the tools proposed by the Cochrane Effective Practice and Organization of Care Group5.

After the initial screening, 10 papers enrolling a total of 734 subjects were included in the analysis. Eight of the included studies were RCTs, while one was an observational study6, and one was a non-randomized pilot study7. OMT's efficacy and/or effectiveness was tested in the treatment of tension-type headache8-11, migraine12, 13, cerebral palsy7, 14, 15, gait analysis in patients affected by Parkinson's Disease6.

The high clinical and methodological heterogeneity of included studies did not allow to perform a meta-analysis, the trials were therefore classified according to the considered condition reporting a narrative summary of results (Table 1), and the overall clinical characteristics and outcome data were presented in a tabular form (Table 2).

Regarding the secondary outcomes, only 40% of the included studies reported data on adverse events: no specific adverse events were recorded among the 296 patients included in the studies.

The general quality of included trials ranged from very low7, to low6, 10, 12, and moderate8, 11, 13-15 according to Cochrane standards.

Results from this review showed that studies on the efficacy and/or effectiveness of OMT treatments are scarce, heterogeneous, and of low methodological quality. No conclusive indication can thus be defined on such basis. Further studies should be carried out considering a more pragmatic methodology, an exhaustive description of all investigated and concurrent interventions, and a systematic report of adverse events, so as to obtain robust and generalizable results.

Table 1

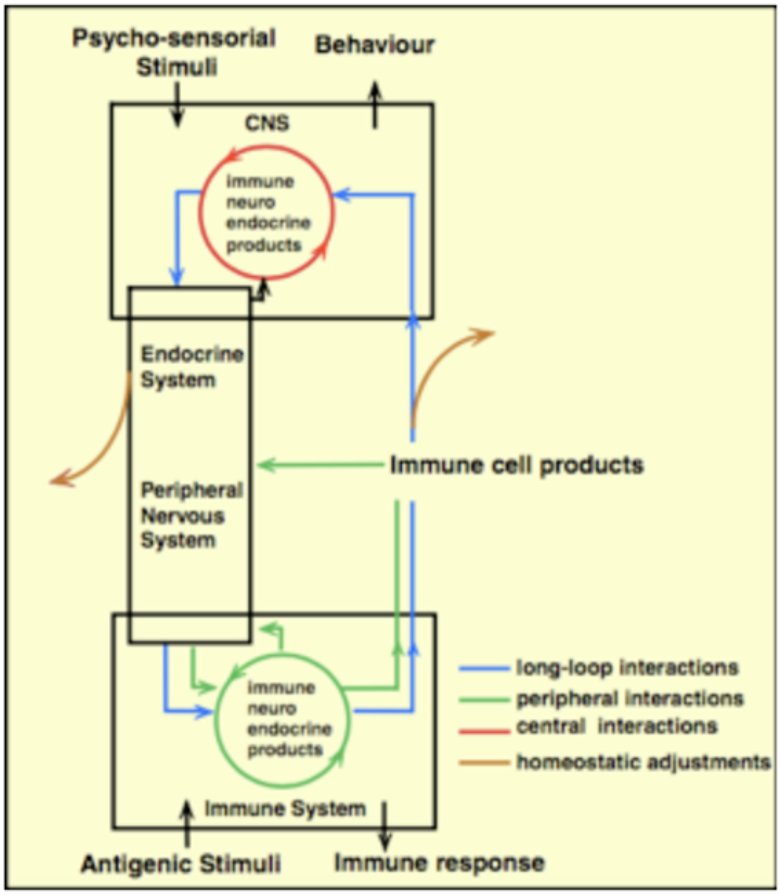
Author/year	Outcome measurements	Results
Accorsi_2014	1) mean changes in Biancardi-Stroppa modified bell cancellation test (accuracy domain) 2) mean changes in Biancardu-Stroppa modified bell cancellation test (rapidity domain)	1) mean [SD] OMT-usual care: 59.2 [17.6] - 42.2 [7.4]; P<.01 2) mean [SD] score OMT-usual care: 116.4 [24.3] - 110.5 [10.5]; P=.14. adverse events: none
Castro-Sanchez_2011	1) baseline pain changes (pressure algometry) on tender points 2) HRV (24-hour Holter) 3) baseline body composition variation (bioelectrical impedance) 4) baseline changes in clinical global impression of improvement (7-Likert scale) 5) baseline changes in clinical global impression of severity (7-Likert scale)	1) significant reduction in number and pain of tender points (p<0.05) 2) No significant variation of HRV within and between groups 3) No significant variation of body composition 4) CST group showed a significant enhancement of clinical global impression of improvement both within group (p<0.05) and versus control (F=6.329; P=0.043) 5) CST group showed a significant reduction of clinical global impression of severity both within group (p<0.05) and versus control (F=5.124; P=0.048)
Wells_1999	1) stride length 2) cadence 3) shoulder velocity 4) arm movement velocity 5) wrist movement velocity 6) lower limb movement velocity	pre-post treatment within OMT-group differences were significant (p<0.05) for all outcomes No statistically significant changes were revealed compared to controls
Anderson_2006 RCT	1) percentage of improvement in HD rating 2) headache degree of improvement based on HI 3) number of free headache days per week 4) intensity of the worst headache of the week	1) mean [SD] OMT-control: 57.6 [27.3] - 15.6 [73.5]; p=0.05 2) mean [SD] OMT-control: 1.9 [1.4] - 0.65 [1.95]; p=0.07 3) mean [SD] OMT-control: 1.8 [1.4] - 0.2 [1.7] p=0.075 4) mean [SD] OMT-control: 1.5 [1] - 0.92 [1.5] p=0.2
Rolle_2014	1) headache frequency, 2) headache pain intensity, 3) over-the-counter medication use 4) HDI	1) OMT vs control: 33% decrease (p<0.001) 2) 20% within OMT group reduction compared to baseline (p<0.001) 3) 45% within OMT group reduction compared to baseline (p<0.001) adverse events: none
Hoyt_1979	1) headache pain intensity 2) EMG	1) pain intensity: among 3 groups: F=17.16 (p<0.001); within OMT group reduction compared to baseline (p<0.001) 2) No significant changes in EMG values on frontalis muscle
Hanten_1999	1) headache pain intensity 2) headache pain affect	Analysis showed a significant improvement for both outcomes in OMT group compared to controls (p<0.05)
Cerritelli_2015	1) HIT-6 score baseline changes 2) days/mo with migraine, 3) severity of pain, 4) amount of rescue medication 5) functional disability, 6) adverse effects of OMT.	1) HIT-6: OMT-usual care: −8.74; −12.96 to −4.52; OMT—sham: −6.62; −10.85 to −2.41; 2) days of migraine: OMT-usual care: M=−21.06; −23.19 to −18.92; OMT—sham: −17.43; −19.57 to −15.29; 3) pain intensity: OMT—sham: RR = 0.42, 0.24 to 0.69; OMT—control: RR = 0.31, 0.19 to 0.49 4) drug consumption: OMT—sham: RR = 0.22, 0.11 to 0.40; OMT—control: RR = 0.20, 0.10 to 0.36; 5) functional disability: OMT-sham: p < 0.001; OMT-control: p < 0.001 6)adverse events: none
Voigt_2011	1) HRQoL, 2) pain intensity, 3) n/days migraine headache 4) working disability 5) German "Pain Questionnaire"	pain intensity: OMT: 66.7 to 53.8 (p<0.05), control: 65.3 to 62.6 (p=0.87) days of migraine: OMT: 23.1 to 19.21 (p=0.31); control: 19.1 to 18.7 (p=0.89) working disability: OMT: 2.5 to 0.5

Table 2

Author/year	Objective	Outcome measurements	Population	Interventions	Control
Accorsi_2014	evaluate the effect of OMT+usual care vs usual care only in subjects with ADHD	1) mean changes in Biancardi-Stroppa modified bell cancellation test (accuracy domain) 2) mean changes in Biancardi-Stroppa modified bell cancellation test (rapidity domain)	N=28 male=82% mean age=8	N=14 Type of intervention: NBT-OMT Type of techniques: myofascial release, cranio-sacral, BMT, BLT Frequency: 6 sessions [2 weekly, 4 biweekly] Session lenght: 40 minutes Study period: 10 weeks	N=14 Type of intervention: usual care + psychological intervention (cognitive-behavioral program) Type of techniques: NA Frequency: by medical procedure Session lenght: NA Study period: 10 weeks
Castro-Sanchez_2011	assess the CST effects on tender points and HRV in adult fibromyalgic patients	1) pain changes (pressure algometry) on tender points 2) HRV (24-hour Holter) 3) body composition (bioelectrical impedance) 4) Clinical global impression of improvement 5) Clinical global impression of severity	N=92 female=100% mean age=52	N=46 Type of intervention: Protocoled CST Type of techniques (in sequential order): 1) still point (in feet), 2) pelvic diaphragm release, 3) scapular girdle release, 4) frontal lift, 5) parietal lift, 6) compression–decompression of sphenobasilar fascia, 7) decompression of temporal fascia, 8) compression–decompression of temporomandibular joint and 9) evaluation of dural tube (balance of dura mater). Frequency: 2/week Session length: 1 hour Study period: 20 weeks	N=46 Type of intervention: sham treatment with disconnected magnetotherapy equipment Frequency: 2/week Session length: 1 hour Study period: 20 weeks
Wells_1999	effects of OMT on gait performances in parkinsonian patients	1) stride length 2) cadence 3) shoulder velocity 4) arm movement velocity 5) wrist movement velocity 6) lower limb movement velocity	N=20 Male=NA Mean age=NA	N=71 Type of intervention: NA Type of techniques: CST Frequency: 3 sessions in 10 weeks, 3 sessions in the remaining study period Session length:NA Study period: 6 months	N=10 Type of intervention: Sham OMT Type of techniques: passive movements Frequency: 1 session [same day] Session length: 30min Study period: IAT
Anderson_2006	compare the effects of OMT and progressive muscular relaxation exercises on patients with tension-type headache	1) percentage of improvement in HD rating 2) headache degree of improvement based on HI 3) number of free headache days per week 4) intensity of the worst headache of the week	N=26 male=NA mean age=NA	N=14 Type of intervention: NBT-OMT Type of techniques: soft tissues, functional, muscle energy, strain/counterstrain, osteoarticular, cranio-sacral Frequency: 3 sessions [weekly] Session lenght: NA Study period: 5 weeks	N=12 Type of intevention: PMR Type of techniques: maximally contract major muscle groups, moving from the feet up to the head, to experience the sensation of the contraction and then the subsequent relaxation or decreased intensity of muscle tension Frequency: daily Session lenght: 20 minutes Study period: 5 weeks
Rolle_2014	efficacy of OMT for pain management	1) headache frequency, 2) headache pain intensity, 3) over-the-counter medication use 4) HDI	N=40 Male=14% mean age=35	N=21 Type of intervention: NBT-OMT Type of techniques: structural, visceral, CST Frequency: 4 weekly sessions Session length: NA Study period: 3 months	N=19 Type of intervention: Sham OMT Type of techniques: CRI evaluation Frequency: 4 weekly sessions Session length: NA Study period: 3 months

9. *"Osteopathic Manipulative Treatment (OMT) in rebalancing of stress axis" – Nicola Barsotti - osteopatianews.net*

The article is divided into two parts. The first section describes the axis of stress in its complexity, placing the emphasis on the facts that this axis shows the global function unit of the organism (indeed it activates the nervous system, the endocrine system, the immunological system, the psychological system and, very important for us, the fascial system). In the second part, instead, is explained how OMT may modulate the activation of the hypothalamic-pituitary-adrenal axis (HPA) and how may activates the parasympathetic nervous system. There are three aspects on which is placed the most attention events: the stimulation of nerve receptors in fascia, the relationship between the nervous and the immune systems and the mechano-trasduction that are capable of modulating gene expression.



10. "PsicoNeuroEndocrineImmunology and science of integrated care, the manual" book chapter on Osteopathy – Nicola Barsotti

The writing of this chapter has had the purpose of making known osteopathy, its paradigms and its main mechanisms of action in the world of medicine and psychology. After a first initial part that tells who was Still and what were the innovative features of his thought in the medical field (of course there is also the description and the explanation of the five models proposed by the Educational Council on Osteopathic Principles - ECOP - of the American Association of Colleges of Osteopathic Medicine like the evolution of the osteopathic philosophy), the chapter develops deepening the main laws of Still in the light of contemporary research: the body as a unit, the body capable of self-healing, structure and function are in mutual relationship. On this last point are briefly described the three main aspects: the three-dimensional structure of the cell; systems of physical connection represented by the ECM; the inter-tissue and the systemic communication. The chapter, then, ends up with a brief discussion on the osteopathic scientific publications.

11. "How Stress Models Body" Marco Chiera, Nicola Barsotti, Diego Lanaro - Pneinews

The article explains how the manual therapies, and specifically osteopathy, can act on regulating the axis of stress intended both as a general and local adaptation. The document continues, then, describing how the reaction of stress may changes the structure of the myo-fascial system (MFS), especially in the case of a moderate but chronic stress and how these changes affect the perception of our body, both through the interceptive and proprioceptive routes. Particular attention has been paid to the activation of Th2 immune circuits, the release of tryptase and chymase enzymes that "prick" the MFS, and the fact that catecholamines, along with orthosympathetic nervous system, contribute to fascial tightness. All this as a result last, change the emotional state of the person, facilitating the appearance of anxiety and pain.