Exploring the utility of motion analysis in osteopathic clinical trials; a school-based pilot study on jaw and cervical range of motion

T. Bagory, P. Vaucher, H. Mhadhbi, M. Menard

Title

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Bagory T.[1], Vaucher P.[2,3], Mhadhbi H.[1], Ménard, M.[1,3,4]

[1]Institut d'Ostéopathie de Rennes – Bretagne (IO-RB), Campus Rennes Atalante Ker-Lann, 50 rue Blaise Pascal, 35170 Bruz (France).

[2]Unit of Research in Mobility & Musculoskeletal Care, School of Health Sciences Fribourg, University of Applied Sciences and Arts Western Switzerland (HES-SO), Fribourg (Switzerland).

[3]Clinical-Human Research Department, Nonprofit Foundation COME Collaboration, Via A. Vespucci 188, 65126, Pescara, Italy.

[4]Univ Rennes, M2S - EA 7470, F-35000 Rennes (France)

Corresponding author: Mathieu Ménard

Institut d'Ostéopathie de Rennes – Bretagne (IO-RB), Campus Rennes Atalante Ker-Lann

50 Rue Blaise Pascal, 35170 Bruz, France.

Mail :menard.m@io-rennes.fr

Title

Exploring the Utility of Motion Analysis in Osteopathic Clinical Trials; a School-Based Pilot Study on Jaw and Cervical Range of Motion.

ABSTRACT

Introduction: This study explores the interest of using motion analysis to evaluate cervical and jaw ROM on students with or without bruxism when comparing Osteopathic manipulative treatment (OMT) to sham in school settings.

Methods: A feasibility study was run with 48 volunteer students from an osteopathic training institution. Random sequence for allocation was generated using a 1:1 ratio and block size of four to either OMT or sham treatment (control group). The chosen motion outcomes of interest were the lateral jaw range of motion, jaw opening, cervical rotation and side-bending. ROM was measured averaging over three repeated movements at baseline, immediately after the 1st treatment, one week before the 2nd treatment, and immediately after second treatment using video-based analysis with 15 body landmarks.

Results: Repeated measures of joint motion at baseline showed high levels of reliability (ICC ranging from 0.953 to 0.985). Motion analysis detected clinically important differences between OMT and sham one-week post-treatment for jaw lateral ROM (3.3°; p=0.018) and cervical rotation ROM (12.0°; p=0.003) on participants with bruxism but not on those without. Magnitude of differences were increased for all parameters following the second treatment (lateral jaw movement; 4.8°, p=0.005; jaw opening; 5.5°, p=0.002; cervical side-bending; 9.2°, p=0.023; cervical rotation; 18.2°, p<0.001).

Conclusion: Motion analysis is capable of detecting the effects of OMT on cervical and jaw ROM in students with bruxism but not without. Finally, the study showed the feasibility of introducing usual standards for clinical trials and sham treatment in school led studies with students.

Keywords: bruxism, osteopathic manipulative treatment, movement analysis, range of motion, cervical spine

INTRODUCTION

Background

Bruxism is a common behaviour that is associated with several other clinical musculoskeletal symptoms (neck pain, headache, tinnitus, sleep disorders, temporomandibular pain, etc.)[1–6]. Its prevalence is similar worldwide and concerns 20% of the population, decreases with age and appears to be very common among students [7–10].

Preliminary studies have highlighted interrelations between cervical spine and jaw musculoskeletal functions [11]. Many associations supported by anatomical, physiological, biomechanical and neurophysiological studies support the idea that the musculoskeletal system of the head, the cervical spine and/or the craniocervical- mandibular system are linked [11–15]. However, other causes that regulate motion, such as central neurological processes, could be at play. Therefore, alternative approaches that address other body regions or use different approaches (ex. mindfulness, stress management, lifestyle change, etc.) could also be beneficial.

Osteopaths make a substantial contribution to primary healthcare provision to a diverse population [16, 17]. This also includes the management of patients with bruxism and neck pain [17–20]. Osteopathy is a person-centred, primary health care discipline that often relies on touch to help to optimize, to restore, and to maintain functional balance and well-being [21, 22].

A large debate persists in the literature about osteopathic ability to evaluate motion and dysfunction; however, most studies agree that osteopathic tests lack fidelity and accuracy [23–26]. Specific and functional tests help osteopaths to analyse and evaluate the structural and functional integrity of the body in line with critical reasoning using osteopathic principles [25, 27]. Osteopathic motion tests remain very subjective and seem inappropriate to detect “somatic dysfunctions” as a simple dichotomous answer [24]. Pattern recognition could be the way clinicians use motion tests thereby making it possible to detect subtler nuances in motion. Tests might be interpreted in a broader manner than we think and also use motion detection to detect abnormal muscular response during active self-induced polyarticular motions. Osteopathic motion tests could falsely target specific joint functions when in reality they provide information on a much more complex motion behaviour. Some behavioural pattern could reveal the intricate relationship of a whole chain of interlinked subcomponents that can only be correctly appreciated when considering motion in its entirety [28–30]. This approach for clinical interpretation is close to Johnston's concept of "*bony segments as mobile units within a mobile system*" [31]. His pioneering work highlighted the importance of interpreting local motion of body parts by using gross motion tests within a broader functional system [32]. Polyarticular motion could therefore help to understand dysfunction and guide treatment. This is of major importance for education and research in osteopathic healthcare [20, 33, 34].

An interesting joint to test this principle is the temporomandibular joint. Some preliminary studies have reported that osteopathic care could decrease significantly cervical spine and/or temporomandibular joint pain [35–39] even if the rationale and mechanics by which osteopathic care may decrease bruxism remains unclear. Previous authors have suggested that osteopathic care could increase spine range of motion [40–43] but few studies have focused on functional assessments on patients with bruxism. This is probably due to the difficulty in objectifying dynamic motion without impeding the movement itself [20, 44]. Detailed range of motion analysis may nevertheless help identify specific patterns of movement alterations that are not easy to identify with other means of measurement. This has now become possible with new methodologies developed in biomechanics and human movement analysis [42, 45, 46]. Video capture systems make it possible to evaluate motion in a constraint-free environment [37, 47, 48].

However, experimental observations are lacking to support the use of such analysis in clinical settings. Motion analysis is expensive, complex, and time-consuming making it difficult to apply in pragmatic clinical trials. However, the applications drawn from motion analysis could bring a better understanding of assessment procedures used in usual care and improve functional global assessment [49–53].

This study aims to investigate whether motion analysis is capable of detecting subtle changes in jaw and cervical motion in a reliable way when comparing OMT to sham therapy and identifying which outcome is best as primary outcome.

METHODS

Trial design

This study consisted of a pilot monocentric 1:1 randomised parallel trial on symptomatic and asymptomatic students. It explores the usefulness of motion analysis for future phase I and II clinical trials. Approval for this study was obtained from the institution's ethical and scientific board of XX. The study was conducted in accordance with the amended Declaration of Helsinki.

Participants, randomization and allocation

Recruitment of participants was conducted through an online questionnaire sent to all 314 students from the Institute. Answers were collected from 124 osteopathic students.

Inclusion criteria were (1) being aged between 18 and 35 years, (2) being a student at the IO-RB, (3) having no musculoskeletal disorders reported in the cervical spine or the jaw, (4) and for the bruxism group, presenting chronic bruxism for more than a year. Exclusion criteria for both groups were: (1) having dental or orthodontic treatment in progress, (2) recent tooth extraction, (3) known disc-condyle disunion, (4) bite splints, (5) orthognathic devices or (6) recent direct trauma.

Self-reported bruxism was not evaluated other than with the questionnaire on symptoms. Symptoms related to TMJ disorders were also ruled out.

Participants received written and oral instructions about the intervention, test protocol, and possible risks and benefits of the study. Students were told that different manual treatment approaches were to be compared without specifically mentioning one of them to be sham. This was necessary to avoid students discussing their treatment and guessing their allocation. Once data collection was over, students were informed of the true nature of both groups. Written informed consent was obtained from all participants before their inclusion in the study.

All participants agreed to avoid other forms of manual treatment during their follow-up and if required to notify this protocol deviation to investigators. Participants in both group bruxism or no-bruxism were randomly allocated in a 1:1 ratio to two sub-groups OMT (Treated Group) or sham treatment (Control Group) using a random sequence of blocks of size 4 generated by R. The study flowchart is presented in Figure 1. Allocation was then attributed following the order of responses to the first online questionnaire. A staff member then prepared the material for the treating osteopaths. Allocation was revealed to the osteopaths on the arrival of each patient when opening each folder.

Interventions

OMT consisted of two treatment sessions (45') separated by seven days that were personalized and included patient history taking, osteopathic diagnostic assessment and OMT. Participants in the treatment group were randomly allocated to one of six osteopaths with over 10 years of practice experience. OMT was tailored for the patient by combining gentle techniques on areas of restriction consisting of articulatory techniques, myofascial release techniques, functional techniques and visceral and cranial techniques, etc. The entire body was included in the osteopathic evaluation and treatment with special attention to the head, jaw and cervico-thoracic areas. Despite some expected variation in their application by different practitioners, all the techniques used were familiar to most recently trained osteopathic practitioners and taught in all French institutions.

Sham intervention (45') included patient history taking, osteopathic diagnostic assessment and two different protocols of three sham manual techniques pseudo-randomly assigned to each participant in order to reproduce, as similar as possible, the contextual variables of the sessions [54]. The sham protocol included palpation and tissue mobilisation that was predefined and targeted to specific regions without intent to change motion. All details about OMT and sham treatment interventions are reported in Table 1 using TIDieR-Placebo guidelines [55].

Outcomes

All participants were assessed four times; first at baseline, then immediately after the first session, then seven days after the first session, and finally immediately after the second session. A research team member who was not involved with the interventions and was blinded to allocations was responsible for collecting all the baseline measures and follow-up outcomes.

The chosen motion outcomes of interest were the lateral jaw range of motion, jaw opening, cervical rotation and side-bending after the 1st and 2nd treatment, and one week after the first treatment. This was done through a video-based system developed for this study. Participants were equipped with 15 body landmarks indexed in Figure 2. Markers trajectories were obtained from three sport cameras (Gopro Hero7Black, Gopro Hero6, Gopro Hero5) placed around the participant. The experimental setup was illustrated in Figure 3.

To evaluate the cervical spinal range of motion, participants were instructed to perform three trials of active maximal side-bending and rotation on each side (right and left). To evaluate jaw range of motion, students were also asked to perform three trials of active open/close and right and left lateral movement of the jaw. A randomized sequence of functional active movement of cervical and jaw movement was proposed for all students. Kinovea® software (v0.8.15) was used to analyse the experimental data and to compute the range of motion of the cervical spine (side, rotation) and the temporomandibular joint (lateral and opening movement of the jaw).

Blinding

The researchers involved in the evaluation procedures had no access to the allocation of the participants. All participants were blinded to group assignment.

Statistical methods

Outliers were defined for each measure and identified. These were most often related to misreading of motion markers which had to be manually framed. Such errors were corrected. Reliability of measures was evaluated using a one-way random-effect model with absolute agreement to calculate intraclass coefficient (ICC) for individual measures before taking their mean. After verifying that the range of motion was similar between the left and right side, a single outcome was summarized by adding ROM from the left to the right side. Baseline comparison between OMT intervention group and the sham group was compared using Student T-test. Linear regression was used to measure between-group differences at follow-up adjusting for baseline values. All analysis were intention-to-treat. Correlation between outcomes was using Pearson correlation coefficients. Differences between students with or without bruxism were evaluated adding an interaction term in the logistic regression. The interaction term identified those who were both in the intervention arm and had symptoms. In other terms, the logistic regression modelled the added effects of treatment in participants with bruxism. Significance level was set at $p<0.05$. No adjustments were made for multiple testing. Sensitivity analysis was done post-hoc to verify that results were consistent even after adjusting for baseline imbalance.

RESULTS

Participants and baseline values

A total of 48 participants were recruited from a XX osteopathic educational institution, the XX, between September and October 2019. Two participants did not attend their appointment (for medical reasons outside the context of the study) and were excluded from further analysis, resulting in a total sample of 23 participants in the bruxism group and 23 participants in the no-bruxism group. All participants received allocated treatments. No major protocol deviation was reported.

Most participants were female (34/46; 73.9%), their age ranged from 18 to 25 years, their BMI was of 22.4 on average (ranging from 18.3 to 32.4 kg/m^2). Details on baseline values for each group are provided in Table 2. Except for cervical rotation in the group with bruxism ($p=0.012$), all other measures were well balanced between groups ($p>0.05$).

Reliability

Repeated measures of joint motion at baseline showed high levels of reliability. Individual measures had an ICC of 0.953 (CI95% 0.925 to 0.972) for jaw lateral movement, an ICC of

0.975 (CI95% 0.959 to 0.985) for jaw opening, an ICC of 0.975 (CI95% 0.959 to 0.985) for cervical side-bending, and an ICC of 0.985 (CI95% 0.975 to 0.990) for cervical rotation.

Objectivation of OMT on jaw lateral movement

One week after treatment, compared to sham, OMT treatment had a significant effect on increasing lateral jaw ROM (+3.3°; CI95% 0.6 to 5.9°; p=0.018) on participants with bruxism (Table 3). This effect was absent in the group without bruxism (-0.4°; CI95% -2.4 to 1.7; p=0.720). Effects of treatment were restricted to those having symptoms. Having bruxism was determinant for OMT to have effects on jaw lateral movement in the studied population (interaction test shows superiority of 4.1°, CI95% 0.9 to 7.2, p=0.012). These results remained similar even after adjustment for baseline imbalance.

Effects on other ROMs

For students with bruxism, at one week, OMT had a significant effect over sham intervention on cervical rotation ROM (+12.0°; CI95% 4.7° to 19.3°, p=0.003), but not on jaw opening or cervical side-bending (Table 3). Similar results were observed for short term effects, immediately after the first treatment with lower magnitudes for cervical rotation (+7.8°, p<0.001) and significant effects for cervical side-bending (+5.2°, p=0.045). Following the second treatment, effects were significant for all parameters (Table 3).

For students without bruxism, compared to sham intervention, at one week there were no effects on jaw opening (+0.4°; p=0.821), cervical side-bending (+0.6°, p=0.851) or cervical rotation (+6.4°, p=0.09). This was also the case in the short term, immediately after treatment and immediately after the second treatment except for cervical rotation which was increased by 10.4° in the OMT group (CI95% 1.7 to 10.0; p=0.021).

Correlations between parameters

Changes over time at one week were correlated between jaw and cervical ROM. Students that gained in lateral jaw movement also gained in cervical side-bending (ρ=0.313, p=0.036) and cervical rotation (ρ=0.378, p=0.010). These same correlations became stronger for students with bruxism (cervical side-bending: ρ=0.595, p=0.003 ; cervical rotation: ρ=0.440, p=0.036) and optimal for cervical side-bending in students with bruxism and OMT (ρ=0.640, p=0.018). In this same sub-population, there was also a correlation between gain in cervical rotation and reduced jaw opening (ρ=-0.567, p=0.043) that was however absent in other students.

Efficacy of blinding

At the 15-day follow-up, participants were asked whether they believed they were in the active or sham group. Proportion of those believing they were in the active treatment group was similar in the OMT group (11/25; 44%) and in the sham group (7/20; 35%; p=0.760).

Adverse events

Adverse events were monitored and self-reported one week after each treatment. No adverse events were reported by the participants.

DISCUSSION

The main finding of this study was that a video-based approach can objectively identify effects of OMT on cervical and jaw range of motion during two sessions of osteopathic care. Results showed that motion analysis made it possible to show that osteopathic manual care, as compared to sham, induces increased cervical and jaw ROM. Results suggest lateral jaw movement to be a good choice for primary outcome in studies evaluating effects of OMT on patients with bruxism. This pilot study also suggests blinding to be feasible using sham treatment on students. Finally, the gain in mobility was correlated between jaw lateral movement and cervical side-bending supporting our initial hypothesis of the interest of investigating movement over more than one joint.

The methodology developed in this study allowed to observe and analyse, through different time intervals measurements, the effect of the osteopathic manual care over time in an outstanding reliable way (ICC>0.95). The consistency of results over-time also suggests that treatment effects are conserved over at least seven days and could be emphasized by a second treatment session (Figure 4). Contrary to clinical motion tests, motion analysis can be an efficient and objective way to evaluate functional changes in movement following osteopathic manual care.

However, our results should be interpreted with caution. Joint range of motion is by no means the only mechanism involved in bruxism and several etiological factors (psychosocial, anatomical, and/or neuromuscular factors) also need to be explored during patient management. Improved range of motion may be simply a surrogate of improved motor control. Functional motion disorders have been shown to be closely related to alteration of motor control, reduced discriminatory sensation, catastrophization, fear-avoidance, and loss of self-confidence [56–58].

However, even if our results support the hypothesis that OMT could alter motor control during movement, they do not make it possible to know whether these changes represent any meaningful change for patients (i.e. reduced jaw tension, reduced pain). Range of motion often investigates movements that are most often not done naturally. The underlying theoretical construct linking range of motion with daily symptoms infers that the underlying changes also affect movement before reaching physiological limits. This assumption was not tested. This would require collecting more descriptive and tangible evidences of individual motor behaviours, not only in a traditional structural model of articular dysfunction but during specific functional motion tests [26]. Also, additional determinants could be explored during functional motion-tests both with instrumental approaches (electromyography – jaw muscle activity) and non-instrumental approaches (self-reported - perceived pain, stress levels and impact on daily life).

Practical applications for education and research

One of the challenges of education is to find a way to facilitate the transition from academic learning to training for their future profession but also to research [59]. Biomechanics has been introduced as an official teaching unit in the education of osteopathic students since 2014 in France [60]. The challenge is to apply both anatomical/physiological bases and mechanical concepts (mathematics and physics) to observe/describe/measure human movement from a number of different applications that cut across the sub-areas of movement sciences (sport, ergonomics, injury, clinical rehabilitation, etc.) [61, 62]. Additionally, new teaching innovative methodologies to evaluate human movement (Wii Balance Board platform, Kinect, smartphone applications, etc.) were proposed to facilitate the comprehension of biomechanics laws/applications and to make it more “touchable” and inform students about these tools and their limits [63, 64]. The challenge is also to educate future osteopaths in the use of objective tools to evaluate their treatments in order to promote research in osteopathy and to transfer knowledge to education and clinical practice [20, 65, 66]. In this sense, a large number of research themes must be proposed involving students and educators to continue building evidence by validating or disproving the knowledge or beliefs related to osteopathic care [3–6, 34]. Future challenges for the profession are to develop collaborations with other disciplines to create new knowledge and the assessment of the effectiveness of osteopathic manual care in the light of scientific methods but also to associate applied biomechanics and neurosciences to propose new findings in the impact of osteopathic healthcare [34, 67].

Limitations

This study involved a modest cohort of 46 students (divided into 4 experimental groups), it would be interesting for future phase 2 and 3 clinical trials to use a similar methodology measuring ROM on a larger population with a follow-up by combining, it with other measurement tools (Patient Reported Outcome Measures, validated questionnaires, electromyography, etc.) to assess the impact of the global effect of osteopathic care on behaviour.

The study also might be limited in external validity given it targets a specific population particularly concerned by bruxism [7, 9, 10]. Slight differences in treatment approaches between osteopaths cannot be ruled out. All six osteopaths however work in the same school clinic and are used to follow similar approaches. Nevertheless, future studies need to consider training osteopaths to assure they deliver similar treatments and include fidelity analysis to verify if treatment was delivered as planned. Even if blinding was assured, the students' response to treatment could be influenced by their familiarity with the discipline and communication between students.

We collected motion with three sport cameras but not really in 3D with an optoelectronic system for example. However, after comparing the data from this study with previous authors who have established an important database on cervical and mandibular kinematics from 22 experimental studies using recognized systems, it appears that the data obtained are close to the standards they established [68, 69]. In this way, we observed in this pilot study, the effect of OMT only in maximal ROM which focuses on assessing the patient's maximum capacity to perform selected active movements. In order to assess dynamic functional behaviour, it could be useful to track/estimate all the 3D kinematic of each degree of freedom to explore the evolution of the pattern of motion during the functional assessment before and after OMT. This appears to be a better way to explore motion behaviour which is used for the quantified analysis of walking, running or rowing for example [70–73]. A potential limitation to future use of motion analysis in clinical trials is the availability and access to sophisticated material and skilled personnel making it possible to acquire meaningful data. Therefore, future studies with optoelectronic, medical system imagery or inertial sensors are needed to go further with the data collection/analysis but also to confirm the benefits of the treatment and the assessment method [74–77]. Finally, the subjectivity of active voluntary movements could have introduced social desirability bias to the observed improvements in ROM due to OMT. New insights on interoceptive perception and the eventual role of osteopathic care in helping solve misrepresentation of one's body perception and movement are promising to the profession [67, 78].

CONCLUSION

This study highlighted that a video-based approach may allow analysing musculoskeletal function of the jaw and cervical spine before and after OMT. Motion analysis can reveal improvements of cervical and jaw ROM following OMT in osteopathic students with bruxism compared to sham treatment. A longitudinal investigation with a larger sample is needed to confirm the benefits of the treatment and the assessment method. These outcomes are promising for future studies investigating the role of osteopathic care in preventing musculoskeletal conditions in people with bruxism.

This approach could be implemented as an additional tool to objectify the effect of osteopathic healthcare and also to the global advancement of the profession in thriving, growing osteopathic research culture necessary in the contemporary health care landscape.

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FIGURES legends

Figure 1. Flowchart of the study.

Figure 2. Diagram and anatomical localization of markers used during the study; THD: Top of head, FHD: Front of head, BHD: Back of head, FNS: Frontonasal suture, LTMJ: Left temporomandibular joint, RTMJ: Right temporomandibular joint, RGA: Right Gonial Angle, LGA: Left Gonial Angle, SIP: Superior incisive point, IIP: Inferior incisive point, RACJ: Right acromio-clavicular joint, LACJ: Left acromio-clavicular joint, MP: Mental protuberance, JN: Jugular notch, T1: First thoracic vertebra.

Figure 3. Experimental set up proposed and developed in this school-based protocol.

Figure 4. Jaw and cervical range of motion in the bruxism group before and after OMT or sham treatment at one week before and after the second treatment session.

Tables

Table 1: Description of the Osteopathic Manipulative Treatment (OMT) and sham interventions (TIDieR-Placebo checklist)

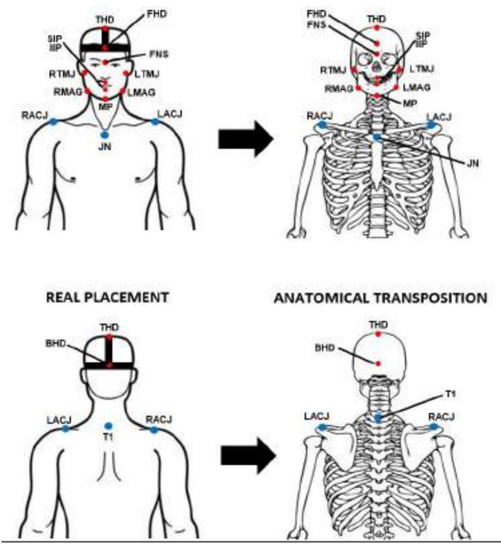
<table>
<tr><th></th><th>OMT</th><th>SHAM</th></tr>
<tr><td>WHY</td><td>Provide usual osteopathic care expected to improve jaw and cervical mobility.</td><td>Account for non-specific, contextual and natural effects and isolate the OMT component of the treatment.</td></tr>
<tr><td>PROCEDURES</td><td>The session was personalized and included patient history taking (past experience, present state), physical examination, diagnostic osteopathic assessment, OMT, counselling, lifestyle change.
Physical examination was done before and after treatment and included observation, global functional tests, pain provocation tests, orientation tests and local regional mobility assessment. Osteopaths were instructed to specifically evaluate jaw, cervical and upper thoracic motion.</td><td>The session was personalized and included patient history taking (past experience, present state), physical examination, diagnostic osteopathic assessment, and two sham procedures that mimicked OMT, counselling, lifestyle change.
Physical examination was done before and after sham treatment and included observation, global functional tests, pain provocation tests, orientation tests and local regional mobility assessment. Osteopaths were instructed to specifically evaluate jaw, cervical and upper thoracic motion.</td></tr>
<tr><td>WHO PROVIDED</td><td colspan="2">Participants were randomly allocated to receive treatment from one of six experienced osteopaths. All practitioners were educators with supervision experience within the school clinic. They had at least 10 years of experience in practice. All osteopaths received the same training for the procedures. There was no calibration on patient management.</td></tr>
<tr><td>HOW</td><td>OMT was personalized for the patient by combining a wide range of osteopathic techniques “as usual” without receiving any instructions on decision criteria. Patient preferences were accounted for. OMT included soft tissue, MET and articulatory techniques, visceral and cranial techniques. Level of patient participation was not standardised across treatments.</td><td>Osteopaths performed a predefined OMT technique on a specific region without any intent to induce changes in tissue mobility.
Sham treatments were administered at two occasions in a random order. The sham treatment was the same for all participants and consisted of:
(1) Palpation of cranial mobility / MET for an inferior glenohumeral / Tissue technique of the 4th Left rib.
(2) Palpation of lower thorax orifice mobility / Soft tissue technique of zygomatic bones / MET on the right 5th rib posterolateral.</td></tr>
<tr><td>WHERE</td><td colspan="2">School clinic</td></tr>
<tr><td>HOW MUCH</td><td colspan="2">Two treatment sessions (45’) separated by one week</td></tr>
<tr><td>TAILORING</td><td>The intervention was adapted and tailored to each participant including anamnesis, tests and treatment. Fidelity to protocol was assessed by analysing the reported interpretation and actions of osteopaths.</td><td>The sham procedure was of two types described above. Fidelity to protocol was assessed by analysing the reported interpretation and actions of osteopaths.</td></tr>
<tr><td>MEASURING THE SUCCESS OF BLINDING</td><td colspan="2">Fifteen days’ follow-up, participants were asked whether they believed they were in the active or sham group.</td></tr>
</table>

Table 2: Characteristics of participants of this study at baseline. * Student T-test

	Group with bruxism			**Group without bruxism**		
	OMT n (%) | mean (SD)	**Sham** n (%) | mean (SD)	**p-value ***	**OMT** n (%) | mean (SD)	**Sham** n (%) | mean (SD)	**p-value ***
Population (N=46)	13	10		12	11	
Sex; female	10 (76.9%)	8 (80%)		8 (66.7%)	8 (72.7%)	
Age (years)	21.2 (± 2.0)	21.0 (± 1.6)		20.7 (± 2.5)	20.3 (± 1.8)	
Weight (Kg)	65.8 (± 15.8)	65.7 (± 13.0)		63.4 (± 6.4)	62.9 (± 9.6)	
Height (cm)	171.4 (± 9.8)	171.5 (± 7.8)		168.2 (± 8.6)	167.2 (± 9.5)	
Promotions						
1st year student	2 (15.4%)	2 (20%)		4 (33.3%)	3 (27.3%)	
2nd year student	2 (15.4%)	4 (40%)		1 (8.3%)	3 (27.3%)	
3rd year student	4 (30.8%)	1 (10%)		1 (8.3%)	2 (18.2%)	
4th year student	5 (38.5%)	3 (30%)		6 (50%)	3 (27.3%)	
Bruxism characteristics						
Bruxism start (past years)	6.9 (± 5.6)	4.8 (± 4.7)				
Static bruxism	7 (53.8%)	6 (60%)				
Dynamic bruxism	1 (7.7%)	0 (0%)				
Mixed bruxism	5 (38.5%)	4 (40%)				
Daytime bruxism	2 (15.4%)	0 (0%)				
Nocturnal bruxism	3 (23.1%)	6 (60%)				
D and N bruxism	8 (61.5%)	4 (40%)				
Dental Health						
Wisdom tooth extraction	10 (76.9%)	5 (50%)		5 (41.7%)	2 (18.2%)	
Other dental extraction	0 (0%)	4 (40%)		1 (8.3%)	1 (9.1%)	
Range of motion (degrees)						
Jaw lateral movement	21.9 (5.3)	24.0 (5.6)	p=0.371	18.2 (3.9)	21.4 (3.5)	p=0.052
Jaw opening	28.4 (4.5)	30.3 (5.4)	p=0.379	31.4 (6.1)	34.6 (7.2)	p=0.266
Cervical side-bending	66.4 (8.0)	74.1 (10.5)	p=0.059	75.2 (6.7)	73.7 (10.2)	p=0.663
Cervical rotation	120.5 (8.8)	132.1 (11.5)	p=0.012	138.9 (14.6)	142.8 (17.8)	p=0.568

Table 3: Gain in jaw and cervical range of motion range from baseline in the group with bruxism at different time points. * Between group difference adjusted for baseline value with positive values representing increased range of motion for OMT group. † Primary outcome

	OMT (n=13) mean (SD)	**Sham (n=10)** mean (SD)	**Difference in changes from baseline*** mean (CI95%; p-value)
Immediately after 1st session (D0)			
Jaw lateral movement (degrees)	25.5° (4.0)	23.6° (5.4)	3.4° (1.0 to 5.8; p=0.007)
Jaw opening (degrees)	30.1° (4.7)	30.6° (5.7)	1.3° (-0.7 to 3.3; p=0.201)
Cervical side-bending (degrees)	72.9° (9.5)	73.9° (8.2)	5.2° (0.1 to 10.2; p=0.045)
Cervical rotation (degrees)	128.2° (11.5)	133.0° (11.4)	7.8° (4.1 to 11.5; p<0.001)
Seven days after 1st session (D7)†			
Jaw lateral movement (degrees)	25.9° (4.2)	24.1° (5.6)	3.3° (0.6 to 5.9; p=0.018)
Jaw opening (degrees)	31.8° (5.6)	31.0 (6.0)	2.7° (-0.02 to 5.5; p=0.052)
Cervical side-bending (degrees)	74.7 (11.1)	76.6 (11.8)	3.2° (-0.8 to 12.5; p=0.080)
Cervical rotation (degrees)	134.7 (13.5)	135.5 (12.5)	12.0° (4.7 to 19.3; p=0.003)
Immediately after 2nd session (D7)			
Jaw lateral movement (degrees)	27.5° (4.4)	24.3° (6.3)	4.8° (1.7 to 8.0; p=0.005)
Jaw opening (degrees)	34.5° (5.6)	30.8° (6.3)	5.5° (2.2 to 8.7; p=0.002)
Cervical side-bending (degrees)	76.9° (12.5)	75.1° (11.0)	9.2° (1.4 to 17.0; p=0.023)
Cervical rotation (degrees)	139.6° (14.7)	135.9° (15.1)	18.2° (9.8 to 26.6; p<0.001)


THD
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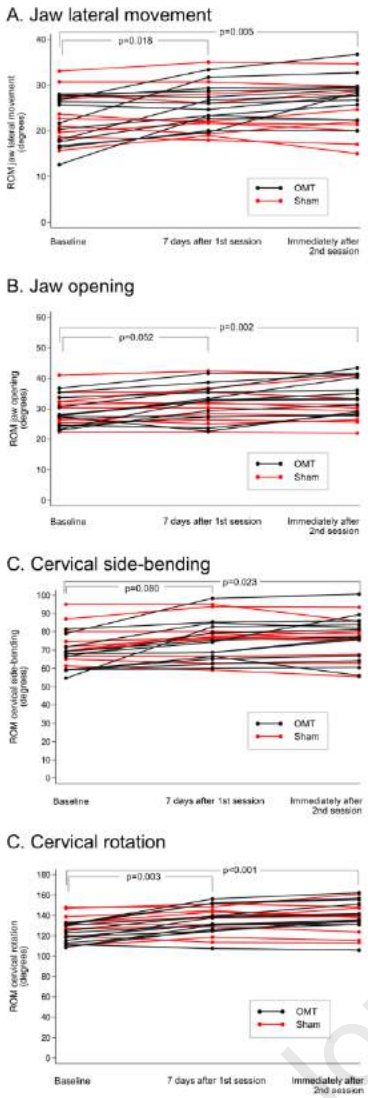
A. Jaw lateral movement
p=0.018
p=0.005
ROM jaw lateral movement (degrees)
OMT
Sham
Baseline
7 days after 1st session
Immediately after 2nd session
B. Jaw opening
p=0.052
p=0.002
ROM jaw opening (degrees)
OMT
Sham
Baseline
7 days after 1st session
Immediately after 2nd session
C. Cervical side-bending
p=0.080
p=0.023
ROM cervical side-bending (degrees)
OMT
Sham
Baseline
7 days after 1st session
Immediately after 2nd session
C. Cervical rotation
p=0.003
p=0.001
ROM cervical rotation (degrees)
OMT
Sham
Baseline
7 days after 1st session
Immediately after 2nd session

CONFLICT OF INTEREST FILE

(1) Conflict of Interest – none

(2) Funding Sources

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(3) Ethical approval details (if applicable) - not applicable

(4) Acknowledgments

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