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Title

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

Bagory T.¹, Vaucher P.^{2,3}, Mhadhbi H.¹, Ménard, M.^{1,3,4}

¹Institut d'Ostéopathie de Rennes – Bretagne (IO-RB), Campus Rennes Atalante Ker-Lann,

50 rue Blaise Pascal, 35170 Bruz (France).

²Unit of Research in Mobility & Musculoskeletal Care, School of Health Sciences Fribourg,

University of Applied Sciences and Arts Western Switzerland (HES-SO), Fribourg

(Switzerland).

³Clinical-Human Research Department, Nonprofit Foundation COME Collaboration, Via A.

Vespucci 188, 65126, Pescara, Italy.

⁴Univ 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.

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2 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.

6 Methods: A feasibility study was run with 48 volunteer students from an osteopathic training 7 institution. Random sequence for allocation was generated using a 1:1 ratio and block size of 8 four to either OMT or sham treatment (control group). The chosen motion outcomes of 9 interest were the lateral jaw range of motion, jaw opening, cervical rotation and side-bending. 10 ROM was measured averaging over three repeated movements at baseline, immediately after 11 the 1st treatment, one week before the 2nd treatment, and immediately after second treatment 12 using video-based analysis with 15 body landmarks.

13 *Results*: Repeated measures of joint motion at baseline showed high levels of reliability (ICC 14 ranging from 0.953 to 0.985). Motion analysis detected clinically important differences 15 between OMT and sham one-week post-treatment for jaw lateral ROM (3.3° ; p=0.018) and 16 cervical rotation ROM (12.0° ; p=0.003) on participants with bruxism but not on those 17 without. Magnitude of differences were increased for all parameters following the second 18 treatment (lateral jaw movement; 4.8° , p=0.005; jaw opening; 5.5° , p=0.002; cervical side-19 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.

24

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

27 INTRODUCTION

28 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].

33 Preliminary studies have highlighted interrelations between cervical spine and jaw musculoskeletal functions [11]. Many associations supported by anatomical, physiological, 34 35 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 36 37 [11–15]. However, other causes that regulate motion, such as central neurological processes, 38 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 39 beneficial. 40

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

52 way clinicians use motion tests thereby making it possible to detect subtler nuances in motion. 53 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. 54 55 Osteopathic motion tests could falsely target specific joint functions when in reality they 56 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 57 58 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 59 60 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 61 62 [32]. Polyarticular motion could therefore help to understand dysfunction and guide 63 treatment. This is of major importance for education and research in osteopathic healthcare 64 [20, 33, 34].

An interesting joint to test this principle is the temporomandibular joint. Some preliminary 65 66 studies have reported that osteopathic care could decrease significantly cervical spine and/or 67 temporomandibular joint pain [35-39] even if the rationale and mechanics by which 68 osteopathic care may decrease bruxism remains unclear. Previous authors have suggested that 69 osteopathic care could increase spine range of motion [40-43] but few studies have focused 70 on functional assessments on patients with bruxism. This is probably due to the difficulty in 71 objectifying dynamic motion without impeding the movement itself [20, 44]. Detailed range 72 of motion analysis may nevertheless help identify specific patterns of movement alterations 73 that are not easy to identify with other means of measurement. This has now become possible 74 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 75 76 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.

85

86 METHODS

87 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.

93

94 Participants, randomization and allocation

95 Recruitment of participants was conducted through an online questionnaire sent to all 31496 students from the Institute. Answers were collected from 124 osteopathic students.

97 Inclusion criteria were (1) being aged between 18 and 35 years, (2) being a student at the IO98 RB, (3) having no musculoskeletal disorders reported in the cervical spine or the jaw, (4) and
99 for the bruxism group, presenting chronic bruxism for more than a year. Exclusion criteria for
100 both groups were: (1) having dental or orthodontic treatment in progress, (2) recent tooth

101 extraction, (3) known disc-condyle disunion, (4) bite splints, (5) orthognathic devices or (6)
102 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.

112 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 113 114 or no-bruxism were randomly allocated in a 1:1 ratio to two sub-groups OMT (Treated 115 Group) or sham treatment (Control Group) using a random sequence of blocks of size 4 116 generated by R. The study flowchart is presented in Figure 1. Allocation was then attributed 117 following the order of responses to the first online questionnaire. A staff member then 118 prepared the material for the treating osteopaths. Allocation was revealed to the osteopaths on 119 the arrival of each patient when opening each folder.

120

121 Interventions

122 OMT consisted of two treatment sessions (45[°]) separated by seven days that were 123 personalized and included patient history taking, osteopathic diagnostic assessment and OMT. 124 Participants in the treatment group were randomly allocated to one of six osteopaths with over 125 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.

132 Sham intervention (45') included patient history taking, osteopathic diagnostic assessment 133 and two different protocols of three sham manual techniques pseudo-randomly assigned to 134 each participant in order to reproduce, as similar as possible, the contextual variables of the 135 sessions [54]. The sham protocol included palpation and tissue mobilisation that was 136 predefined and targeted to specific regions without intent to change motion. All details about 137 OMT and sham treatment interventions are reported in Table 1 using TIDieR-Placebo 138 guidelines [55].

139

140 *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) placedaround the participant. The experimental setup was illustrated in Figure 3.

To evaluate the cervical spinal range of motion, participants were instructed to perform three 152 153 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 154 right and left lateral movement of the jaw. A randomized sequence of functional active 155 156 movement of cervical and jaw movement was proposed for all students. Kinovea® software 157 (v0.8.15) was used to analyse the experimental data and to compute the range of motion of the 158 cervical spine (side, rotation) and the temporomandibular joint (lateral and opening movement 159 of the jaw).

160

161 Blinding

162 The researchers involved in the evaluation procedures had no access to the allocation of the163 participants. All participants were blinded to group assignment.

164

165 *Statistical methods*

166 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. 167 168 Reliability of measures was evaluated using a one-way random-effect model with absolute 169 agreement to calculate intraclass coefficient (ICC) for individual measures before taking their 170 mean. After verifying that the range of motion was similar between the left and right side, a 171 single outcome was summarized by adding ROM from the left to the right side. Baseline 172 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 173 174 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.

182

183 **RESULTS**

184 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.

191 Most participants were female (34/46; 73.9%), their age ranged from 18 to 25 years, their 192 BMI was of 22.4 on average (ranging from 18.3 to 32.4 kg/m²). Details on baseline values for 193 each group are provided in Table 2. Except for cervical rotation in the group with bruxism 194 (p=0.012), all other measures were well balanced between groups (p>0.05).

195

196 *Reliability*

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

199 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.

201

202

203 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 ($+3.3^\circ$; 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.

211

212 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).

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2	2	4

225 Correlations between parameters

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

233

234 *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).

238

239 Adverse events

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

242

243 **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).

279

280 Practical applications for education and research

281 One of the challenges of education is to find a way to facilitate the transition from academic 282 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 283 284 2014 in France [60]. The challenge is to apply both anatomical/physiological bases and 285 mechanical concepts (mathematics and physics) to observe/describe/measure human 286 movement from a number of different applications that cut across the sub-areas of movement 287 sciences (sport, ergonomics, injury, clinical rehabilitation, etc.) [61, 62]. Additionally, new 288 teaching innovative methodologies to evaluate human movement (Wii Balance Board 289 platform, Kinect, smartphone applications, etc.) were proposed to facilitate the 290 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 291 292 future osteopaths in the use of objective tools to evaluate their treatments in order to promote 293 research in osteopathy and to transfer knowledge to education and clinical practice [20, 65, 294 66]. In this sense, a large number of research themes must be proposed involving students and 295 educators to continue building evidence by validating or disproving the knowledge or beliefs 296 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 297 298 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 osteopathichealthcare [34, 67].

301

302 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.

309 The study also might be limited in external validity given it targets a specific population 310 particularly concerned by bruxism [7, 9, 10]. Slight differences in treatment approaches 311 between osteopaths cannot be ruled out. All six osteopaths however work in the same school 312 clinic and are used to follow similar approaches. Nevertheless, future studies need to consider 313 training osteopaths to assure they deliver similar treatments and include fidelity analysis to 314 verify if treatment was delivered as planned. Even if blinding was assured, the students' 315 response to treatment could be influenced by their familiarity with the discipline and 316 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

324 be useful to track/estimate all the 3D kinematic of each degree of freedom to explore the 325 evolution of the pattern of motion during the functional assessment before and after OMT. 326 This appears to be a better way to explore motion behaviour which is used for the quantified 327 analysis of walking, running or rowing for example [70–73]. A potential limitation to future 328 use of motion analysis in clinical trials is the availability and access to sophisticated material 329 and skilled personnel making it possible to acquire meaningful data. Therefore, future studies 330 with optoelectronic, medical system imagery or inertial sensors are needed to go further with 331 the data collection/analysis but also to confirm the benefits of the treatment and the 332 assessment method [74-77]. Finally, the subjectivity of active voluntary movements could 333 have introduced social desirability bias to the observed improvements in ROM due to OMT. 334 New insights on interoceptive perception and the eventual role of osteopathic care in helping 335 solve misrepresentation of one's body perception and movement are promising to the 336 profession [67, 78].

337

338 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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352 **REFERENCES**

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584 FIGURES legends

585

586 **Figure 1.** Flowchart of the study.

587 Figure 2. Diagram and anatomical localization of markers used during the study; THD: Top

588 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,

590 LGA: Left Gonial Angle, SIP: Superior incisive point, IIP: Inferior incisive point, RACJ:

591 Right acromio-clavicular joint, LACJ: Left acromio-clavicular joint, MP: Mental

592 protuberance, JN: Jugular notch, T1: First thoracic vertebra.

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

594 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.

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1 Tables

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3 Table 1: Description of the Osteopathic Manipulative Treatment (OMT) and sham

4 interventions (TIDieR-Placebo checklist)

	OMT	SHAM			
WHY	Provide usual osteopathic care expected to improve jaw and cervical mobility.	Account for non-specific, contextual and natural effects and isolate the OMT component of the treatment.			
PROCEDURES	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.	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.			
WHO PROVIDED	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.				
HOW	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.	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.			
WHERE	s	ichool clinic			
HOW MUCH	Two treatment sessions (45') separated by one week				
TAILORING	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.	The sham procedure was of two types described above. Fidelity to protocol was assessed by analysing the reported interpretation and actions of osteopaths.			
MEASURING THE SUCCESS OF BLINDING	Fifteen days' follow-up, participants were ask	ed whether they believed they were in the active or sham group.			

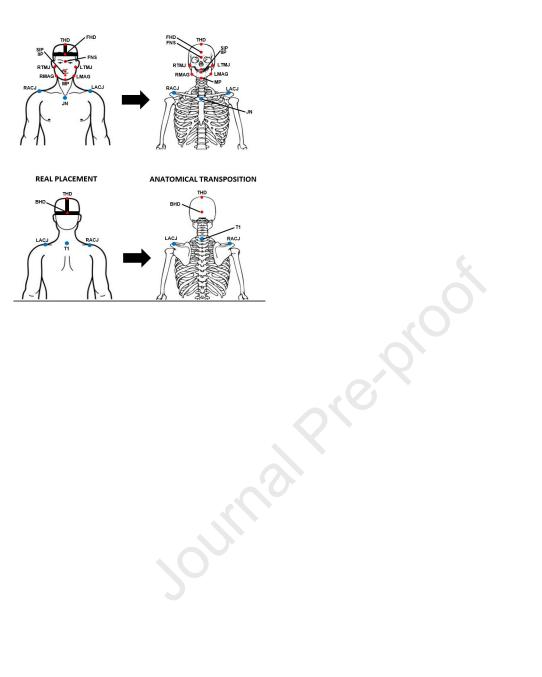
 Table 2: Characteristics of participants of this study at baseline. * Student T-test

	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	60(+56)	1.9(1.1.7)				
years) Static bruxism	$6.9 (\pm 5.6)$	4.8 (± 4.7) 6 (60%)				
Dynamic bruxism	7 (53.8%) 1 (7.7%)	0 (00%)				
Mixed bruxism	5 (38.5%)	4 (40%)				
Daytime bruxism	2 (15.4%)	4(40%) 0(0%)				
Nocturnal bruxism	2 (13.4%) 3 (23.1%)	6 (60%)				
D and N bruxism	8 (61.5%)	4 (40%)				
	8 (01.5%)	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
- 11 bruxism at different time points. * Between group difference adjusted for baseline value with
- 12 positive values representing increased range of motion for OMT group. † Primary outcome

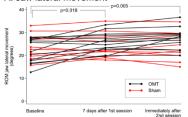
		OMT (n=13) mean (SD)	Sham (n=10) mean (SD)	Difference in changes from baseline* mean (CI95%; p-value)
Imm (D0)	ediately after 1st session			
	Jaw lateral movement (degrees)	25.5° (4.0)	23.6° (5.4)	3.4° (1.0 to 5.8; p=0.007)
	Jaw opening (degrees)	30.1° (4.7)	30.6° (5.7)	1.3° (-0.7 to 3.3; p=0.201)
	Cervical 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)
Sever (D7) [†]	n days after 1st session			
	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)
Imm (D7)	ediately after 2nd session			
	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)

Journal Pre-proof

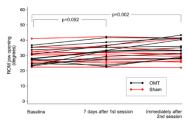


Journal Pre-proof

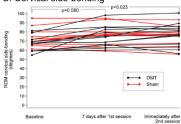
A. Jaw lateral movement



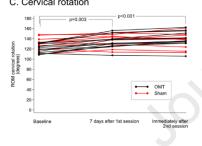
B. Jaw opening



C. Cervical side-bending



C. Cervical rotation



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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