



# A Study to Investigate the Effect of 'Frontal Lift' Osteopathic Manipulative Technique (OMT) in Patients with Chronic Sinusitis

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## Introduction

Chronic sinusitis (CRS) also referred to as rhinosinusitis is a condition involving inflammatory disease of the nose and paranasal sinuses as defined by the Royal College of Surgeons guidelines (RCS) 2016 and cited in earlier research by Mendez-Sanchez et al. [1] and recent research Bergmark & Pynnonen [2]. The etiology of chronic sinusitis is largely unknown or believed to be multifactorial; with inflammation, infection and obstruction of sinus ventilation suggested by RCS (2016). CRS is subcategorized as with and without polyps (Rosenfeld, 2015). CRS can cause two or more persistent symptoms (one of which must be nasal obstruction and/or nasal discharge and/or facial pain/pressure or loss of smell) that last for more than 12 weeks (NICE, 2018) unlike acute sinusitis which has an infective a etiology and commonly resolved within 12 weeks of onset. CRS affecting 1 in 10 UK adults cited the RCS (2016), is reported to have a significant impact on health-related quality of life, high health-care provision and significant days lost to industry.

Primary care for CRS often involves saline irrigation, nasal steroid spray, or both. The repeated use of antibiotics for CRS in primary is not recommended due to limited evidence of efficacy (RCS, 2016, p.6; UWS, 2017, p.47) Surgery for secondary care in UK (RCS) 2016 and similar in US cited in University of Western States (UWS) Clinical Standards, Protocols, and Education (CSPE) Care Pathway (2017). It appears that both the Primary clinical practice guidelines (CPGs) from the RCS (2016) and UWS CSPE Care Pathway (2017) recommend long-term use of nasal steroid spray for CRS. Bergmark & Pynnonen [2] cited few studies have examined the uptake of this recommendation. However, Chong et al. [3] found there was an increased risk of epistaxis (high quality evidence).

Osteopathy is a system of diagnosis and treatment for an extensive range of medical conditions GOC [8], but high-quality evidence research has been moderate for the efficacy of osteopathic manipulative technique (OMT), with most studies only pointing for relieving low back pain Licciardone et al. [13,14] More recent research on OMT to the head region is based on anatomical, physiological, neurological, vascular, muscular, articular and lymphatic systems Louveau et al. [16]. The rigorous studies of concept or efficacy for OMT have not been robust, as OMT has traditionally had an empirical basis rather than a research basis Ching [3].

The objective of this review focuses on the effectiveness of OMT in certain studies and articles which were assessed using a critical appraisal tool (CASP, 2018). As there is scarce evidence based systemic reviews and meta-analyses in OMT from randomized control trials (RCT's) to measure the efficacy of OMT on sinus pain and the beneficial outcomes in the United Kingdom, and so the search was expanded to include other manual therapies in European and United States.

Paul, Buser [19] identified the use of OMT (by Osteopathic physicians) in an emergency department for patients with low back pain, chest pain, torticollis, asthma and sinusitis demonstrated related symptoms could be ameliorated or eliminated with OMT. Orlandi et al. (2016) cited both CRS and asthma frequently co-exist in the same patient affected by similar triggers and co-factors, therefore treating either one of the conditions often has a beneficial effect on both. Raghavan and Jones (2000) found that there was

little evidence to support the effect of complementary therapies (including osteopathy) over those of the placebo effect, cognitive dissonance and the natural resolution of many disease processes. Folweiler and Lynch (1995) demonstrated nasal specific technique as part of a chiropractic approach may be useful in treating CRS and sinus headache. Lee-Wong et al. [12] study of patients with CRS in outpatient allergy clinic, found OMT utilising direct pressure and sinus drainage technique improved sinus pain/congestions in patients. Jeffrey, et al. (2012) carried out a feasibility study of impact of integrative East-West medicine on Sino nasal symptoms and quality of life for patients with chronic sinusitis.

Mendez-Sanchez et al. [1] study suggested that manual therapy (including manipulation) treatment could be considered as an appropriate alternative treatment of chronic sinusitis. The University of Western States (UWS) Clinical Standards Care Pathway (2017) recommended 2 specific procedures out of 5 were upper cervical spine manipulation (joint dysfunction may be present as a viscera-somatic response to sinus irritation and Eustachian tube manipulation (Eustachian tube dysfunction often a comorbid condition of sinusitis), others were rapid dilation the nasal passages (not sinus balloon dilation); facial massage; lymph drainage and percussion recommended for management of CRS. The more recent observational case control study Petersen et al. [20] of neck pain and cervical musculoskeletal dysfunction, common among patients with self-reported sinus headaches maybe a contributing factor to headaches attributed sinusitis. This highlights a potential research to identify a wider population that could benefit from OMT for pain relief with less medication.

### Literature Review

Lee-Wong et al. [12] an allopathic physician (studied OMT during her post-doctoral training) carried out a pilot study on 15 patients (who requested alternative therapies for CRS pain relief) to determine the efficacy of OMT as an adjunct to allopathic therapy to possibly minimize the use additional pain medications for relief of CRS discomfort symptoms. One OMT session only comprising of four direct pressure and 'milking' techniques and a sinus drainage technique (a total of 6 maneuvers) for nasal congestion carried out on patients as described in DiGiovanna & Schiowitz [28] or a total of 18 minutes of treatment. The results reported decreased sinus pain/congestion after OMT.

### Limitations

- The outcome is not statistically significant  $p=0.0012$  ( $p<0.0001$  is significant)
- Small sample size-15 patients.
- No control groups included (sham treatment or no treatment for the control group). A suggestion of sham treatment or no treatment for the control groups can provide a new factor to the two groups (Denscombe, 2017). However, difficulty in proving osteopathy efficacy via RCT's due to the impossibility of double blinding and difficulties in conducting ineffective sham treatments Licciardone & Russon [13].
- Only a pain scale symptom score card was used for patients before and after OMT. A Sino nasal Outcome Test

Questionnaire (SNOT-22) a widely used, self-administered, quality of life questionnaire for patients with CRS could be included for understanding specific patient-reported outcomes. The history and severity of symptoms not included therefore data is difficult to compare in relation to normative data for chronic sinusitis patients.

- There was no follow up with CRS patients to see how long the improvement of pain lasts.

### Strengths

- This study supports the perpetual argument in the context of more research into the effectiveness of OMT. An allopathic doctor who is interested in OMT and initiated this research for CRS patients with sinus pain. As suggested by King [11] an opportunistic study for encouraging interprofessional dialogue that will enhance the public acceptance of the services of all professions who use their hands in healthcare.
- A relatively short trial just one session but effective in highlighting and advocating OMT that are commonly taught and used in osteopathic medicine.
- Potential for further research on OMT that were integral part of osteopathic approach and principle in manual medicine Ward & Greenman [31,34].

Mendez-Sanchez et al. [1] A prospective case series study in reporting manual therapy carried out on 14 patients diagnosed with CRS with craniofacial pain. The rationale of the applied manual therapy is based on the premise that inadequate drainage preventing resolution of sinusitis; the autonomic nervous system is influenced by the imbalance of adrenergic, cholinergic, and sensory components; it seems that the parasympathetic stimulation increases nasal-mucosa secretions, whereas sympathetic stimulation causes circulatory vasoconstriction within the nose and sinuses. Hence the reasoning that manual therapy interventions targeting the thoracic and upper cervical segments with spinal manipulation as well as craniosacral treatments may influence the sympathetic and parasympathetic systems and ultimately have a positive effect on the autonomic nervous system. Hence integrating manual therapy with the overall management of symptoms associated with CRS may allow for reduced use of prescription medications.

The manual techniques include:

- Thoracic spinal manipulation applied over T1-T3;
- Manipulation of the cervicothoracic junction;
- Manipulation of the pelvic girdle;
- Decompression of the temporomandibular joint;
- Myofascial release of the anterior cervical region;
- Myofascial release of the hyoid system;
- Mobilization of the maxilla bones;
- Mobilization and compression of the frontal bone.

The trials carried out for 7 weeks. Treatment carried out in Session 2, 3 and 5, evaluation only in session 1, 4, 6 and 7. Outcome measure shown a difference after treatment same for pain scores and pressure pain threshold (PPT). The results reported decreased sinus pain/congestion after OMT.  $P < 0.0015$ .

**Limitations**

- a. The outcome is not statistically significant  $p < 0.0015$  ( $p < 0.0001$  is significant)
- b. Small sample size-14 patients
- c. No control groups included, cause and effect relationship cannot be determined
- d. Complex outcome measures-3 questionnaires and pressure algometry testing at each session.
- e. No indication of how long each treatment session took.

**Strengths**

- a. Treatment was based on the presentation of the symptoms of the patient on each session.
- b. A combination of local and regional manual therapy interventions appeared to yield improvements in all outcome measures.
- c. Manual therapy interventions for patients appeared to fair better than when similar patients are treated with antibiotic drugs or endoscopic surgery.
- d. Standardized evaluation methods with all sessions for each patient at the same period in the afternoon to reduce a confounding temporal effect
- e. Potential for further research to look at medium- and long-term effects of manual therapy.

Jeffrey et al. (2012) carried out prospective, non RCTs to establish the feasibility of studying the impact of integrative East-West medicine (IEWM) on Sino nasal symptoms and quality of life (QoL) on patients with CRS. Acupuncture, Acupressure, dietary modification and advice on stress management were introduced in addition to the standard medical therapeutic regimen.

**Limitations**


- a. Not RCTs and absence of control groups.
- b. Bias selection of study population.
- c. Too many modalities of treatment were carried out.
- d. Not an efficacy analysis but to obtain an estimate of the effect size and variance necessary to plan a definitive study to test and refine individual components of the IEWM protocol.
- e. Small sample size-11 patients.

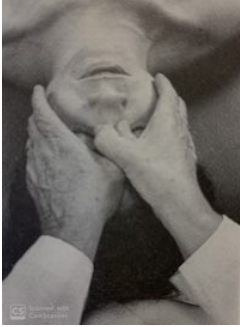
**Strengths**

- a. First study using Integrated two health care systems – Preliminary data indicates IEWM may improve symptoms and Quality of Life (QoL) for patients with CRS for future research
- b. Over 8 weeks of regular reproducible treatment
- c. Potential further research integrating OMT and Acupuncture

In summary, there is limited osteopathic research carried out with use of OMT to help reduce CRS and symptoms. The results showed deficiencies in the study design for Systemic Review and Meta-Analysis, the lack of control group in the RCTs. Nevertheless, the studies in this review have shown a clear justification the potential use of OMT along with traditional allopathic medicine, either locally Lee-Wong et al. [12] or locally and regionally Mendez-SSanchez et al. [1] to help easing sinus pain and congestion.

**Appendix 1A:** 'frontal lift' OMT versus combined OMT.

OMT	Procedure	Time
 <p>Streamlined 'frontal lift' to coronal suture</p>	<ul style="list-style-type: none"> <li>• With the patient supine the operator stands at the head of the couch;</li> <li>• With the head supported to avoid extension, the operator places the finger pads of his index and mid fingers under the patients supra orbital ridge, care being taken not to contact their eye</li> <li>• Gentle pressure is then applied to lift the frontal bone from the nasal and ultimately the ethmoid, which can be re-enforced by the operator</li> <li>• gently gripping the upper aspect of the nose with their thumb and index finger. Thereby opening the sinus ostium;</li> <li>• The technique can be re-enforced by holding back on the nasal bone;</li> <li>• Re-assess.</li> </ul> <p>Lintonbon (2013)</p>	<p>3 mins</p>

 <p>Sinus drainage for nasal congestion</p>	<ul style="list-style-type: none"> <li>• The nasal passages are milked by the examiner placing the thumb of the right hand on the left side of the patient's nose and the left thumb on the right side of the nose, thumbs crossing above the bridge of the nose.</li> <li>• Pressure is applied alternately by each thumb, moving down the length of the nose.</li> <li>• This is done several times, then the thumbs are reversed, and a sweeping motion is made bilaterally down the sides of the nose and out over the maxillae.</li> </ul> <p>DiGiovanna (1991, p.361; 2005)</p>	<p>3 mins</p>
<b>Total OMT time</b>		<b>6 mins</b>

Lee-Wong et al. [12] offers a viable opportunity for further research. Building on from this study by investing the effect of 'frontal lift' OMT - a craniosacral technique to release restricted side of the frontal bone to achieve balance of both sides to affect sinus congestion in the ethmoid or frontal sinuses cited in DiGiovanna & Schiowitz [28,29] and Greenman [31], the potential benefits of using a streamlined technique requiring less treatment time, may improve patients' comfort. Therefore, affording the practitioner more time available to treat the patient's other tissues causing symptoms. This streamlined 'frontal lift' OMT to coronal suture claims to open the coronal suture and therefore opens the drainage passages of all sinuses as shown by Lintonbon [15]-See Appendix 1A-to ease facial-maxillary sinus headache. Hence this study is to test the streamlined 'frontal lift' OMT use on its own is sufficed, comparing with the combined OMT (Appendix 1B) for CRS patients. Therefore, a shorter treatment time by 60% (reduced from 18 mins to 6 mins). Thereby enhancing patient comfort (Appendix 1A).


**Aim of the Quantitative study**




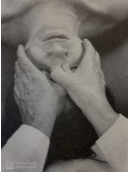
The main aim of this study is to investigate the effect of 'frontal lift' OMT compared with combined OMT (direct pressure and "milking" techniques and sinus drainage technique) in easing CRS and congestion.

**Objectives of Quantitative study**

From the studies reviewed, a sample size with minimum 16 participants have been chosen. 2 experimental groups, 1 control group. Sample size of 48.

- To collect data obtained using a Sino nasal Outcome Test Questionnaire (SNOT-22)
- To use a Numeric Pain Rating Scale (NPRS) experienced by the participants, before and after the application of the 'frontal lift' technique on its own compared with pain experienced by participants before and after the application of the 'combined techniques' (direct pressure and "milking" techniques and one sinus drainage technique)
- From the data collected from the 2 experimental groups and a control group, it could be determined which is the more effective technique (s) to reduce symptoms of pain and congestion with chronic sinusitis
- To select participants and randomly allocate them into 2 different groups, Group A&B as well as a Control Group
- To apply 'frontal lift' technique to Group A; to apply 'combined techniques (direct pressure and "milking" techniques and sinus drainage technique) to Group B and Control Group with sham treatment or no treatment
- To compare SNOT-22 questionnaire pre and post treatment and NVPR scores between Group A, Group B and Control Group
- To analyses the data obtained from the SNOT-22 from the 3 groups
- To determine if the 'frontal lift' OMT on its own is just as effective as using a combined OMT (direct pressure and "milking" techniques and a sinus drainage technique) in easing sinus pain and congestion (Appendix 1B).

<b>Appendix 1B: 'Frontal lift' OMT versus Combined OMT.</b>		
<b>OMT</b>	<b>Procedure</b>	<b>Time</b>
 <p>Direct pressure applied over the frontal sinuses</p>	<ol style="list-style-type: none"> <li>1. Direct pressure applied with the thumbs over the frontal sinuses</li> <li>2. Gradual increase and release pressure in a gentle, rhythmic motion, never hard enough to cause severe pain</li> <li>3. Repeat the cycle several times</li> <li>4. Place thumbs side by side in centre of forehead, downward gentle pressure, move laterally towards the temporal fossae, the thumbs directed caudad to the zygoma</li> <li>5. Repeat cycle 6 to 8 times</li> </ol> <p>DiGiovanna (1991, p.360; 2005)</p>	<p>3 mins</p>

 <p>Gentle pressure applied over the supraorbital notch</p>	<ol style="list-style-type: none"> <li>1. Gentle pressure applied over the supraorbital</li> <li>2. Then the thumbs swept along the eyebrow ridge bilaterally</li> </ol> <p>DiGiovanna (1991, p.360; 2005)</p>	<p>3 mins</p>
 <p>Pressure applied over the maxillary sinuses</p>	<ol style="list-style-type: none"> <li>1. Pressure applied over the sinuses with the thumbs</li> <li>2. The nasal passages are "milked" by beginning with the thumb on each side of the nose and pressing down while sweeping the thumbs laterally along the maxilla</li> </ol> <p>DiGiovanna (1991, p.360; 2005)</p>	<p>3 mins</p>
 <p>Direct pressure applied over the temporal areas</p>	<ol style="list-style-type: none"> <li>1. Pressure applied over the temporal areas by gently placing the thenar eminences in the temporal fossae bilaterally</li> <li>2. Compressing these areas between the hands</li> <li>3. Pressure is applied and released in gentle, rhythmic motions</li> </ol> <p>DiGiovanna (1991, p.360; 2005)</p>	<p>3 mins</p>
 <p>Sinus drainage for nasal congestion</p>	<ol style="list-style-type: none"> <li>1. The nasal passages are milked by the examiner placing the thumb of the right hand on the left side of the patient's nose and the left thumb on the right side of the nose, thumbs crossing above the bridge of the nose.</li> <li>2. Pressure is applied alternately by each thumb, moving down the length of the nose. T</li> <li>3. This is done several times, then the thumbs are reversed, and a sweeping motion is made bilaterally down the sides of the nose and out over the maxillae.</li> </ol> <p>DiGiovanna (1991, p.361; 2005)</p>	<p>3 mins</p>
<p><b>Total OMT Time</b></p>		<p><b>18 mins</b></p>

**Experimental hypothesis**

Using a 'frontal lift' OMT is just as effective at reducing the painful symptoms in chronic sinusitis patients at the LSO Clinic, London, in comparison to patients receiving a combined OMT.

**Null hypothesis**

Using a 'frontal lift' OMT is less effective at reducing the painful symptoms in CRS patients at the LSO Clinic, London, in comparison to patients receiving a combined OMT.

**Approach & Methodology**

The research strategy adopted in this study is a quantitative research approach utilizing a Randomized Controlled Trials (RCTs) experiment design to test the hypothesis. Randomized study design reduces bias and a rigorous tool to examine cause-effect relationships between an intervention and outcome

Hariton & Locascio [9]. Other advantages include repeatability of identical procedures, precision and consistency in gathering of data. However, Denscombe [27] also cited disadvantages such as artificial settings, ethics in this instance, the use of control groups with sham or no treatment, therefore control of the relevant variables maybe difficult to achieve. The difficulties in constructing a sham technique, if all touch especially the face can induce reward or placebo - induced pain control, then differentiating the effects of OMT and a sham technique can prove to be tricky (Petrovic, et al., 2002; Zubieta, et al., 2005).

**Methods-Participants**

My sample size of 48 participants will be determined through LSO Clinic (3 groups of 16 participants in each group). There will be 2 groups of CRS participants and a control group receiving no treatment or sham treatment (Table 1).

**Table 1:** Eligibility Criteria of Participants for Chronic sinusitis.

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• Adult males and females aged over 18</li> <li>• Any ethnic background, sexual orientation and religious beliefs</li> <li>• Participants who are experiencing 12 weeks or longer of 2 or more of the following signs and symptoms:                             <ul style="list-style-type: none"> <li>o mucopurulent drainage (anterior, posterior, or both)</li> <li>o nasal obstruction (congestion)</li> <li>o facial pain-pressure-fullness, or</li> <li>o decreased sense of smell</li> </ul> </li> <li>• Commitment for participant availability in the study</li> <li>• Strong understanding of the English language</li> </ul>	<ul style="list-style-type: none"> <li>• Minimum age over 18</li> <li>• Had contraindications for manual therapy, including spinal manipulation</li> <li>• Had history of cranial, facial or neck surgery</li> <li>• Had complications associated with CRS</li> <li>• Taking prescription medications for their presenting symptoms during the study</li> <li>• Had received manual therapy interventions for their condition within 2 months before the study</li> <li>• Refrain from starting any new therapeutic interventions or medications during their participation</li> <li>• Have any co-existing conditions that may impact on their ability to interact in conversation</li> <li>• Limited mental capacity to give informed consent through verbal and written information</li> <li>• Current critical stage of their condition making them unable for participation</li> </ul>

**Methods-Study Design**

Building on from Lee-Wong pilot study a more ‘robust’ study design to include:

1. Participants in the study will be seen once a week for 6 weeks.
2. The use of SNOT-22 before treatment at each week. (Appendix 2)
3. The use of NPRS before and after end of treatment from the 1st week to 6th week to observe an improvement in easing

sinus pain and congestion. (Appendix 3). The Numeric Pain Rating Scale (NPRS) has good sensitivity and generates data for analysis Karcioğlu et al. [10].

4. Bigger sample size-48
  - a. Streamlined frontal lift’ OMT (Group A)-16 people-treatment time: 6 mins each
  - b. Combined OMT (Group B)-16 people-treatment time: 18 mins each
  - c. Control group (Group C-sham or no treatment)-16 people

**Methods-Outcome Measures**

**Appendix 2A:** The Sino nasal Outcome Test-22 Questionnaire (SNOT22).

Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale	No problem	Very mild problem	Mild or slight problem	Moderate problem	Severe problem	Problem as bad as it can be
1. Need to blow nose	0	1	2	3	4	5
2. Sneezing	0	1	2	3	4	5
3. Runny nose	0	1	2	3	4	5
4. Cough	0	1	2	3	4	5
5. Post-nasal discharge (dripping at the back of your nose)	0	1	2	3	4	5
6. Thick nasal discharge	0	1	2	3	4	5
7. Ear fullness	0	1	2	3	4	5
8. Dizziness	0	1	2	3	4	5
9. Ear pain/pressure	0	1	2	3	4	5
10. Facial pain/pressure	0	1	2	3	4	5
11. Difficulty falling asleep	0	1	2	3	4	5
12. Waking up at night	0	1	2	3	4	5
13. Lack of sleep	0	1	2	3	4	5
14. Waking up tired	0	1	2	3	4	5
15. Fatigue	0	1	2	3	4	5
16. Reduced productivity	0	1	2	3	4	5
17. Reduced concentration	0	1	2	3	4	5
18. Frustrated/ restless / irritable	0	1	2	3	4	5
19. Sad	0	1	2	3	4	5
20. Embarrassed	0	1	2	3	4	5
21. Sense of taste/smell	0	1	2	3	4	5
22. Blockage/ congestion of nose	0	1	2	3	4	5
TOTAL						

In order to select 48 patients clinically diagnosed with CRS, a Sino nasal Outcome Test Questionnaire (SNOT-22)- Appendix 2-is chosen based on the highest quality for understanding specific

patient-reported outcomes during the management (PROM) of chronic sinusitis (CRS) showed in a recent systemic review Rudmik et al. [22] (Table 2 & Appendix 2a).

**Table 2**

PROM	Development score	Psychometric score	Overall Quality score
CSS	4	6	10
RSOM-31	8	2	10
RSDI	5	5	10
SNOT-16	1	3	4
SNOT-20	4	6	10
RSI	2	2	4
RhinoQoL	6	5	11
RSTF symptom score	5	0	5
<b>SNOT-22</b>	<b>9</b>	<b>10</b>	<b>19</b>
SNQ	4	3	7
DyNaChron Questionnaire	4	6	10
<b>QOD</b>	<b>7</b>	<b>7</b>	<b>14</b>
Adelaide DSS	6	1	7
EQ-5D for CRS	9	4	13
<b>SCT</b>	<b>8</b>	<b>6</b>	<b>14</b>

Source: Rudmik, et al. (201) Summary of quality scores for each PROM

CSS, Chronic Sinusitis Survey; DSS, Disease Severity Score; DyNaChron, Dysfonctionnement Nasal Chronique Questionnaire; RhionQoL, Rhinosinusitis Quality of Life Questionnaire; RSDI, Rhinosinusitis Disability Index; RSI, Rhinosinusitis Severity Inventory; RSOM-31,31-item Rhinosinusitis Outcome Measurement; RSTF, Rhionsinusitis Task Force; SNOT, Sinonasal Outcome Test; SNQ, Sinonasal 5-item questionnaire.

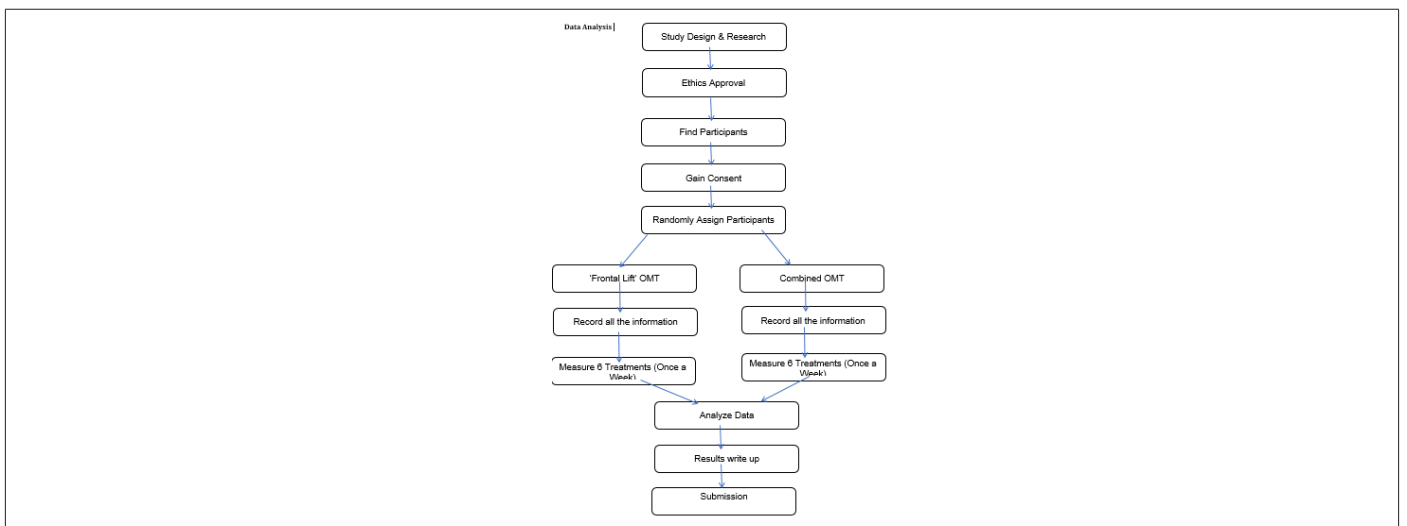
The independent variable includes ‘frontal lift’ OMT and combined OMT which allow the researcher to consider if either one of the two OMT techniques leads to the dependent variable in reduction of pain symptoms. Most importantly, the researcher must investigate whether the independent variable of OMT influences the dependent variable to agree with its experimental hypothesis.

**Data Analysis**

The data from the SNOT-22 and NPRS will be analysed using SPSS Version 24 software, because of its extensive statistical data analysis capability, as well as effective data management within an excel format (Stehlik-Barry and Babinec, 2017). It will be accessed

and interpreted as ordinal data through extensive statistical analysis by using the SPSS software. Using the nomogram (Field, 2017) data will be analysed along this type of format: Ordinal data → Differences between groups → Dependent → ordinal rank → Non-parametric (rank test Wilcoxon matched pairs signed) → Non-Parametric (Friedman’s 2-way analysis of variance by ranks).

The sum test (Wilcoxon rank) will check the frequency of conditions between the two groups e.g. amount of pain reduction. The Friedman’s test will compare the division of the 2 quantitative variables, with analysis of variance (ANOVA) for dependent samples (Flow chart).



### Resources Required

- a. The Sino nasal Assessment Questionnaire (SNOT-22)
- b. Numeric Pain Rating Scale (NPRS)
- c. SPSS Version 24 Software-download from ARU
- d. Access to room at LSO clinic for treatment process

- e. Poster advertisements (including any exclusion criteria) of the study placed in LSO's reception waiting area to invite volunteers to participate in the study.
- f. Letter and Consent form (see ethical issues-checklist no.2) (Appendix 2b).

**Appendix 2B:** Numeric Pain Rating Scale (NPRS).



### Literature Search Strategy

An extensive literature search was conducted using several search databases with access gained via Anglia Ruskin University Library, using MEDLINE, PubMed, Google scholar, Science Direct, Cochrane database/library, and Europe PMC. The keywords used (in various combinations) to search the literature were: osteopathic, medicine, osteopathy, Rhinosinusitis, sinusitis, sinus, adult sinusitis, headache, asthma, pain, craniofacial pain, pressure, neck, manipulation, chronic, manipulative, treatment, effects, manual,

therapy, techniques, allergy, chiropractic, quality of life, review, outcome, measures, alternative, complementary, randomized controlled trials. Boolean operators (AND and OR) were used e.g. Osteopath# AND Sinus#.

Also, London School of Osteopathy (LSO) library resources were used to access hard copy materials such as books and journals for additional evidence (Table 3 & 4). The database search dates were conducted from March 9th -1st May 2019 for further citations of this research.

**Table 3:** Inclusion and Exclusion criteria for relevance.

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• Published Systemic reviews, primary research, experimental study, articles, case studies, books, commentaries</li> <li>• English studies, clinically relevant to this topic.</li> <li>• Time limit for the publication date of 10 years, unless it's older and still relevant</li> <li>• Emphasis on literature from within the UK and studies from other geographical regions.</li> </ul>	<ul style="list-style-type: none"> <li>• Children Sinusitis</li> <li>• Non-English publications/studies of different physical therapies irrelevant to this research.</li> <li>• Sources focused on osteopathic treatment towards other pathological conditions aside from Sinusitis would be inconsistent with the research data.</li> <li>• Exclusion of unpublished osteopathic studies.</li> <li>• Articles that was purely theoretical.</li> </ul>

**Table 4:** Literature search strategy.

Type of research	Number of papers
Systematic Reviews/Meta-Analysis	6
Randomized Control Trials	3
Questionnaires/Survey	1
Case Control Studies	4
Case Studies	2
Narrative Review	2
Books	5
<b>TOTAL</b>	<b>23</b>

### Osteopathic Relevance

DiGiovanna et al. [28] found that chronic sinusitis is almost always associated with somatic dysfunction of the cervical spine. Sympathetic innervation to the sinuses arises from the upper thorax and travels through the cervical region. Hence treating cervical somatic dysfunction and performing sinus drainage

techniques helps to relieve pain and as well as assist in the drainage of the sinuses. These techniques used are fully explained in most osteopathic handbooks. However, none of them fully explain the effectiveness of one technique over another. This study is to investigate a shorter treatment with one technique as opposed to using several. This would deliver maximum pain relief from OMT



and therefore improve the patients' comfort leading to improved treatment outcome in a shorter time scale allowing the practitioner to work on associated tissues causing symptoms.

From a quantitative perspective, the study design will contribute towards creating additional research towards the field of osteopathy by assessing if a streamlined OMT is just as effective compared with a combined OMT technique therefore potentially to improve patients' comfort with less treatment time. This could support the relevance of osteopathy in establishing whether this manual technique 'frontal lift' can be a significant factor contributing towards an individual's health. Osteopathy is widely used as a therapeutic tool; however, its reliability as a form of treatment remains unconfirmed. Therefore, research regarding chronic sinusitis treatment using OMT should be conducted to highlight future research priorities.

## Limitations

Despite the best intentions and following the guidelines, the lack of recent research in the osteopathic field. Hence the generation of a hypothesis from the data collected is rather subjective. Also, the use of a placebo, control group and sham treatments have been overlooked/not included by the researchers in the reviewed articles.

## Conclusion

The use of 'frontal lift' OMT appears to be less invasive and suitable for a wide range of CRS patients. The shorter the time of treatment allowing the practitioner to work on the potential maintaining factors thereby working on the body as a whole – one of the core principles of osteopathy. The extra time generated also allows the practitioners to explore the patient's biopsychosocial aspects of the patient.

## Ethical Issues -Checklist (Table 5).

<b>All ethics must be approved by the ethics committee and faculty of health sciences in Anglia Ruskin University (ARU) (Scott, 2016).</b>	
1.	Participants are invited for voluntary participation when attending the LSO clinic. This is handled through LSO clinic office to avoid coercion.
2.	A Participant Information Sheet with a consent form (to be signed by all participants) providing participants with adequate information about the research and risks, e.g. possible side effect after treatment; state commitment required for the number of treatments; state right for withdrawal from participation at any time without penalty and obtain informed consent from participants. Adequate timing for participants to decide and discuss this with family and friends first before proceeding.
3.	All fairness and equality is ensured for all participants.
4.	Anonymity to be assured by allocating a number instead of a using the patient's name.
5.	Patients understand that participation is voluntary, have the right to withdraw at any time without affecting patient's future treatment experiences.
6.	Health and Safety Risk Assessment completed to ensure that patients' comfort and that they do not undergo psychological trauma as a result of the treatment.
7.	Any complaints from the study should be handled through ARU procedures.
8.	All data collected needs to comply with latest GDPR. The information must be kept on password-protected computer. Collected data will be held securely according to the Data Protection Act 1988. The confidentiality of participants is assured as collected information will be anonymised and the data is only available to the researcher. The data will be destroyed after the study has ended.
9.	The study will be covered by Anglia Ruskin University insurance once ethical approval is obtained.
10.	All participants are entitled to their feedback results via email or post.

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