# **Masters Project**

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# THE EFFECT OF OSTEOPATHIC

# TREATMENT ON PEOPLE WITH CHRONIC &

# SUB-CHRONIC NECK PAIN

#### <u>Abstract</u>

**Background and Objectives:** Neck pain is a common problem within our society, and can be severely disabling and costly to the sufferer. The aim of this single cohort study was to investigate the effect of Osteopathic management of sub-chronic and chronic neck pain on perceived pain and disability.

**Methods:** Seventeen participants (mean age  $34.8 \pm 11.9$ , 7 Male, 10 Female) who had experienced intermittent or constant neck pain for a duration of longer than one month (mean duration of symptoms ( $168.8 \pm 292$  weeks) were included in this study. The participants were offered a four-week course of osteopathic treatment at the Victoria University Osteopathic Medicine Clinic and were treated by senior osteopathic students using a semi-standardised treatment protocol. A Visual Analogue Scale (VAS), and Neck Disability Index (NDI) were completed prior to the initial treatment and after treatments on weeks 2 and 4.

**Results:** Analysis with a one-way repeated measures ANOVA revealed statistically significant difference between pre and post VAS scores ( $F_{1.62, 25.92} = 36.007, p < 0.001$ ) for the VAS scores. Post-hoc analysis (paired t-tests) showed the difference to be between pre and post4 week groups and pre and post 2 weeks groups. Similarly, analysis of the NDI scores revealed significant differences between pre and post scores ( $F_{2.32} = 14.629$ , p < 0.001) and post-hoc analysis (paired t-tests) showed the difference to be between pre and post4 week groups and pre and post 2 week groups. When the cohort was divided into chronic (symptoms longer than 52 weeks) and sub-chronic (symptoms present for less than 52 weeks) sub-groups, both groups were found to have significant decreases in VAS and NDI scores from pre treatment to post 4 weeks.

**Conclusion:** Perceived intensity of neck pain, and perceived disability significantly reduced following four weeks of osteopathic management. This pilot study suggests that osteopathic treatment is effective for the management of chronic and sub-chronic neck pain

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#### <u>Introduction</u>

Neck pain is a common problem within our society. In a sample of 10,000 adults 34% reported that they had experienced neck pain in the previous year.<sup>1</sup> Like low back pain, neck pain can be a significant health and economic burden to the sufferer, and is a frequent source of disability.<sup>2</sup>

The effect of pain and/or stiffness of the neck may affect the individual's physical and social functioning considerably, and interference and hindering of the sufferer's every day activities can be a source of much anxiety and stress for the individual. Neck pain is a common cause for work absence for this reason, and in some industries it even accounts for as many absences from the workplace as low-back pain.<sup>2</sup>

Chronic pain has been defined as being pain present for at least three months, or when a patient suffers a continuous, or essentially continuous, but low level exacerbations of pain (each of which may be referred to as "acute") or recurrent pain for a period greater than 12 months.<sup>3</sup> The temporal parameters that denote the change from acute to chronic pain range from 3 to 12 months, and the ambiguity in definition has led to the proposal of clinical terms like subacute and subchronic pain.<sup>4, 5</sup> Sub-chronic pain is characterised as constant pain for a duration of five to seven weeks, but no longer than 12 weeks or recurrent pain for a period less than 12 months.<sup>3, 5</sup>

The aetiology of neck pain is contentious. Bogduk<sup>6</sup> states the aetiology of neck pain is a disorder of the cervical spine, and it can refer from various anatomical structures that are nociceptive and thus capable of producing pain. Studies have confirmed that pain can be evoked in fascia, tendons, periosteum, aponeurosis, joint capsules, synovium and the outer 1/3 of the anulus.<sup>6</sup> Other causes of neck pain include systemic arthritic disease, thoracic outlet syndrome (or costo-clavicular syndrome), direct trauma, upper respiratory tract infection, fibromyalgia and congenital agenesis of cervical spinal structures,<sup>7</sup> or referred pain from throracic structures, and the upper limb.

Osteopathic treatment of the cervical spine has been claimed to greatly assist the healing of injury, pathology, or dysfunction of the cervical region.<sup>8</sup> No study has examined the effect of osteopathic treatment on neck pain, but several researchers have examined the effect of isolated manual therapy techniques.

Hoving et al<sup>9</sup> compared the effectiveness of manual therapy (passive articulatory mobilization) on non-specific, sub acute neck pain (symptoms of at least 2 weeks duration) with physical therapy (in which neck exercises were prescribed and guided by the therapist without manual therapy), and ongoing medical doctor treatment (which involved the prescription of pain medication and anti-inflammatory drugs, hot compresses, rest, and home exercises.) 183 patients rated their perceived recovery on a 6-point ordinal scale, ranging from "much worse" to "completely recovered." In addition, on the basis of the systematic assessment of spinal mobility, palpation, and pain reported by the patient, the research assistant rated the severity of physical dysfunction on a

numeric 11-point scale. Functional disability was measured according to the Neck Disability Index (NDI). At the end of 7 weeks, the researchers found that 68.3% of the manual therapy patients felt "much improved" or "completely recovered," compared with 50.8% in the physical therapy group and 35.9% in the medical doctor group. Although the physical therapy group scored slightly better than continued care, none of the differences were statistically significant. Unfortunately Hoving's study did not provide a true indication of the effectiveness of each intervention (eg physiotherapy alone,) as each group's intervention was contaminated by interventions of the other groups.

High Velocity Low Amplitude (HVLA) manipulation has also been reported to benefit patients with neck pain. Pikula,<sup>10</sup> in a pilot study, found that a single manipulation reduced pain intensity, measured using a Visual Analogue Scale (VAS), and a greater range of motion using the CROM instrument in patients with acute neck pain. They found that HVLA applied to the side of neck pain was more effective than when applied to the side opposite the pain, or to a placebo group.

Jordan and colleagues<sup>11</sup> compared physical therapy (articulatory mobilisation), intensive strengthening of the cervical musculature, and high velocity manipulation on 119 patients with chronic neck pain. All three treatment interventions demonstrated meaningful improvement in self-reported pain (VAS), disability (NDI), medication use, patient satisfaction, and physician's global assessment. Patients were assessed at enrolment and at completion of the study. Secondary outcome measures included active range of motion of the cervical spine as well as strength and endurance measurements of the cervical musculature. Postal questionnaires were used for 4- and 12-month follow-up assessments and the improvements were maintained at 4- and 12-month follow-up. However, whether the improvement was a result of treatment or simply a result of time is unknown because there was no significant difference between treatment groups, in pain, disability, medication use or cervical range of motion.<sup>11</sup>

Bronfort<sup>12</sup> conducted a randomized, single-blinded clinical trial using 191 patients with chronic neck pain. After a 1-week baseline period, patients were to receive 11 weeks of therapy, consisting of either 20 sessions of spinal manipulation (high velocity low amplitude - HVLA) combined with rehabilitative neck exercise (spinal manipulation with exercise), MedX rehabilitative neck exercise, or spinal manipulation (HVLA) alone. The main outcome measures were patient-rated neck pain (VAS), neck disability (NDI), functional health status (as measured by Short Form-36 [SF-36]), global improvement, satisfaction with care, and medication use. Range of motion, muscle strength, and muscle endurance were assessed by examiners blinded to group assignment. All three groups showed significant improvement in all outcome measure scores, and these improvements were maintained at 1 year follow-up. Statistically significant differences among groups were seen only for satisfaction ratings, which were highest in patients in the combination manipulation and exercise group.<sup>12</sup>

The available literature suggests that manual therapy is an effective alternative therapy to orthodox medical treatment in the management of neck pain, and may too be a more cost effective option<sup>13</sup>. Ingeborg<sup>13</sup> examined the cost effectiveness of physiotherapy (including

active and postural or relaxation exercises, stretching, and functional exercises) manual therapy (muscular mobilisation (soft tissue stretching and kneading), specific articular mobilisation, coordination or stabilisation exercises) and general practitioner care (self care being heat application, home exercises and ergonomic considerations) for 183 patients with chronic neck pain. They found that the manual therapy group showed a significant greater improvement in outcome measures than the physiotherapy group and the general practitioner care group, while the cost effectiveness ratios and the cost utility ratios showed that manual therapy was less costly and more effective than physiotherapy or general practitioner care.<sup>13</sup>

Osteopathic treatment consists of a combination of a wide range of manual techniques, including soft tissue technique, passive mobilisation (articulatory) technique, high velocity technique (HVLA), functional (indirect) technique, myofascial release technique, craniosacral technique and muscle energy technique.<sup>14</sup> Although several studies have investigated the effect of specific treatment techniques on neck pain, there has been little investigation of the effect of osteopathic management, incorporating many of the above mentioned techniques. The aim of this pilot study was to examine the effect of osteopathic management on patients with subchronic or chronic neck pain.

#### <u>METHODOLOGY</u>

#### Participants

Twenty-one participants were recruited from Victoria University staff, students and from businesses in the Melbourne CBD. Four participants presented for the initial visit but did not attend for further treatment or to complete any post-treatment questionaries, so were excluded from the study, leaving a final sample of seventeen volunteers (mean age  $34.8 \pm 11.9$ , 7 Male, 10 Female.) Participants were included in the study if they were experiencing intermittent or constant neck pain for a duration of longer than one month and excluded if they had suffered constant unremitting neck pain for greater than twelve months, had any neurological signs and symptoms, suffered from cervical intervertebral disc prolapse, or any trauma such as whiplash. Volunteers currently receiving regular manual therapy were also excluded, and one volunteer was excluded for this reason. To further examine the influence of chronicity of symptoms, the cohort group was divided into two sub-groups for further analysis, one group being chronic pain sub-group, (which was defined as recurrent symptoms lasting greater than 12 months), and the other sub-group being sub-chronic (less than 12 months duration).<sup>4,5</sup>

#### <u>Measures</u>

Treatment outcomes were measured using the Neck Disability Index (NDI) and Visual Analogue Scale (VAS). The NDI was modelled after the Oswestry index and developed by Vernon and Mior.<sup>16</sup> The NDI's validity and reliability have been confirmed by a randomized controlled trial (r = 0.89).<sup>16</sup>

Just as in the Oswestry, participants choose the statement that best describes their situation in each of ten sections. The sections concern impairments such as pain (including headaches), and abilities to perform tasks like personal care, lifting, reading, driving, and recreation. Clinicians score each statement just as they do the Oswestry. Total scores can range from 0 (highest level of function) to 50 (lowest level of function), and "percentage of disability" scores are calculable.

The Visual Analogue Scale (VAS) was used to measure the quantity of volunteers' perceived pain. The VAS consists of a 10 cm horizontal line with two endpoints, being extremes "no pain" and "worst pain ever." The subject is requested to place a mark corresponding to the pain level that they averaged during a one week interval, which has been shown by Bolton et al<sup>17</sup> to be more sensitive to changes in pain than when compared to measuring the present pain. The distance from the low end is measured to give a numerical index of pain severity. This tool can introduce some bias, but advantages lie with in the ease and brevity of the administration and scoring. The VAS is a very reliable and valid measure for pain intensity (r = 0.79)<sup>18</sup> and responsiveness to change.<sup>17</sup>

The choice of a Visual Analogue Scale (VAS) and a Neck Disability Index (NDI) for collecting data on pain and disability was made because both are reliable, valid,<sup>16, 17, 18</sup> and commonly used tools for measuring pain and disability in clinical practice.<sup>9, 10, 11, 12</sup>

#### **Procedures**

Advertising flyers were posted to local businesses in the CBD and a global email was circulated to all VU students and staff. Interested individuals were posted information sheets and consent forms. The Victoria University ethics committee granted ethics approval for all components of this study.

The participants were offered a four-week course of osteopathic treatment at the Victoria University Osteopathic Medicine Clinic (OMC). Participants were requested to complete the NDI and VAS pre treatment, at 2 weeks and at 4 weeks on completion of treatment. The first consultation of the trial replicated an initial consultation for any new patient presenting to the OMC. The practitioners were four senior Osteopathic students (5<sup>th</sup> year) who performed the treatments under the supervision of a registered Osteopath. Participants were screened for vertebral artery insufficiency as outlined by Gibbons and Tehan.<sup>19</sup>

A semi-standardised treatment protocol was used, aspects of which were used at the practitioner's discretion, based on clinical findings on examination. This protocol included the following elements:

- Soft Tissue technique (cross fibre kneading, stretching) to trapezius, cervical/thoracic erector spinae, levator scapulae, and sub occipital muscles.<sup>14</sup>
- 2. Articulation (passive joint mobilisation) to the cervical and thoracic spine.<sup>14</sup>

- Muscle energy technique (MET) to stretch the scalenes, levator scapulae, trapezius, SCM muscles.<sup>14</sup>
- 4. Counterstrain technique.<sup>14</sup>
- 5. HVLA to the cervical and thoracic vertebrae.<sup>20</sup>

All the techniques in the treatment protocol are commonly advocated in current osteopathic texts. <sup>14, 20</sup>

Participants were requested to undertake osteopathic treatment twice a week for 2 weeks, and once a week for the following 2 weeks. Participants were requested to complete the questionnaire prior to the initial treatment and post treatment at weeks 2 and 4. After the 4 week trial period, the scores from the questionaries were analysed and compared for pre and post differences, using a one-way repeated measures ANOVA, and post-hoc testing with paired t-tests. The one-way repeated measures ANOVA is an appropriate method for analysing data with more than one post intervention measurement.

#### <u>Results</u>

#### Participant details:

The cohort group mean age was 34.8 ( $\pm$  11.9) years and the mean duration of symptoms was 168.8 ( $\pm$ 292) weeks. The cohort group was divided in to a subchronic group (N=10) where duration of symptoms was less than 52 weeks, and a chronic group (N=7) where duration of symptoms was greater than 52 weeks. The mean age of the subchronic was 33.6 ( $\pm$ 11) yr and the gender ratio was 1:1. The mean age of the chronic sub-group was 36.5 ( $\pm$ 13.7) years and the mean duration of symptoms was 376 ( $\pm$ 376) weeks and included 10 females and 7 males. Four of the seventeen participants did not return for their final visit or to complete post-treatment questionnaires at week 4, and the missing data were replaced with series means.

#### VAS Scores

VAS data for the cohort group showed an overall decrease in mean scores from pre treatments (mean = 6.53, SD = 3.09) to week 2 (mean = 2.41, SD = 2.06), and from week 2 to week four (mean = 1.47, SD = 2.07). Analysis of the data for the cohort group with a one-way repeated measures ANOVA showed Mauchly's test of sphericity to be violated (p=0.047), and thus indicated that there was not a normal distribution of the data. The Huynh-Feldt adjustment of degrees of freedom was then used to analyse the ANOVA, showing significant differences between time groups ( $F_{1.6, 25.9}$  = 36.007, p< 0.001). Posthoc testing with a paired t-test showed the differences to be between pre and post 2 groups (p< 0.001), pre and post4 groups (p< 0.001). No significant difference was seen between post 2 and post 4 weeks (p= 0.055). There was a large effect size (Cohen's d) for the VAS in the group total (d= 1.57).

Analysis of the VAS scares for the sub-chronic group with a one-way repeated measures ANOVA determined there were significant differences between time groups ( $F_{2, 18}$  = 18.76, p< 0.001). Post-hoc testing using a paired t-test showed the differences to be between pre and post2 groups (p= 0.001), pre and post4 groups (p= 0.001). No significant difference was seen between the post2 and post4 weeks (p= 0.080). Analysis of the VAS scores for the chronic group with a one-way repeated measures ANOVA showed Mauchly's test of sphericity to be violated (p= 0.144), and thus indicated that there was not a normal distribution of the data. The Huynh-Feldt adjustment of degrees of freedom was then used to analyse the ANOVA and determining that there were significant differences between time groups ( $F_{1.51, 9.05}$ = 25.71, p< 0.001). Post-hoc testing using a paired t-test showed the differences to be between pre and post2 groups (p= 0.003) and pre and post4 groups (p= 0.001). No significant difference was seen between the post2 and post4 weeks (p= 0.077).

#### **NDI Scores**

NDI data for the cohort group showed an overall decrease in mean scores from pre treatments (mean = 22.81, SD = 12.61) to week 2 scores (mean = 15.08, SD = 11.38), and from week 2 scores to week four scores (mean = 8.58, SD = 7.93). Analysis of the data for the total group with a repeated measures ANOVA determined there were significant differences between time groups ( $F_{2,32}$  = 14.629, p< 0.001). Post-hoc testing with a paired t-test showed the differences to be between pre and post2 groups (p= 0.001), pre and post4 groups (p< 0.001), and post 2 and post 4 weeks (p= 0.030). There was a large effect size (Cohen's d) for the NDI in the group total (d= 1.12)

The sub-chronic group showed a decrease in mean scores over time (pre=21.5, post 2=15.64, and post 4= 8.2213). Analysis with a one-way repeated measures ANOVA showed Mauchly's test of sphericity to be violated (p= 0.055), indicating that there was not a normal distribution of the data. The Huynh-Feldt adjustment to degrees freedom

was utilised for the analysis of the ANOVA, which showed that this decrease in mean scores was significant ( $F_{1.5, 13.1} = 4.701$ , p = 0.038). Post hoc analysis using t-tests showed the significant differences to be between pre and post 2 weeks (p = 0.033), between pre and post 4 weeks (p = 0.031) No significant difference was found between post 2 and post 4 weeks.

The chronic group also displayed a similar trend of decreasing mean NDI scores over time (pre = 26.38, post 2=15.10, post 4=5.95) A one-way repeated measures ANOVA indicated that Mauchly's test of sphericity was violated (p=0.636), indicating that there was not a normal distribution of the data. The Huynh-Feldt adjustment to degrees freedom was utilised for the analysis of the ANOVA, which showed significant differences between time groups (F<sub>2, 12</sub>=14.306, p= 0.001) Further post hoc analysis (ttest) showed the significant differences to be between pre and post 2 weeks (p= 0.011), between pre and post 4 weeks (p= 0.002) but not between post 2 and post 4.

Mean	Ν	Age	duration of symptoms
Total	17	34.8±11.9	168.8±292
Sub Chronic	10	33.6±11	23.8±17
Chronic	7	36.5±13.7	376±376.6

Table 1 – Subject mean age and duration of symptoms (weeks)

#### Table 2 –VAS Scores

VAS	Pre	2weeks	4weeks
Total	6.5±3.09	2.4±2	1.4±2
Sub Chronic	6.02±3.4	2.31±1.8	1.5±1.9
Chronic	7.2±2.7	2.4±2.5	$1.5 \pm 2.5$

#### Table 3 – NDI Scores

NDI	Pre	2weeks	4weeks
Total	22.8±12.6	15.1±11.4	8.6±7.9
Sub Chronic	21.5±15.9	15.6±13.5	8.2±8.06
Chronic	26.4±7.9	15.7±9.5	5.9±8.4

#### **Discussion**

Osteopathy is a form of manual therapy often used to treat complaints relating to the musculoskeletal system. Although there is limited evidence of the effectiveness of individual manual techniques, there remains a lack of convincing evidence that osteopathy as a whole can have a positive influence on neck pain.<sup>10, 11, 12, 13</sup> The present study demonstrated that osteopathic treatment is able to significantly reduce neck pain and disability in the cohort, as well as in the chronic and sub-chronic subgroups. The results obtained in this trial showed significant decreases in mean scores post treatment and large effect sizes, suggesting clinically relevant changes to pain intensity and disability.

Analysis of both VAS and NDI scores demonstrated significant changes suggesting that osteopathic treatment for 4 weeks used in this setting on 17 volunteers experiencing neck pain reduced the individuals' pain, and the effect of pain on daily activities such as driving, reading, working and self care. The mean VAS scores showed significant reduction from pre treatment and week 2, and pre treatment to week 4, and, although the mean scores decreased, changes between 2 weeks and 4 weeks scores were not statistically significant.

The NDI for the cohort showed significant changes between the pre treatment score and the post 4 weeks scores, and between pre and post week 2, but no significant change between post week 2 and post week 4. With the results for both VAS and NDI showing that between weeks 2 and 4 the change was not significant, it is notable to mention that between weeks 2 and 4, the volunteers only received one treatment per week, whereas in the initial two weeks they were receiving two treatments per week. It should be noted, however, that the minimum detectable change (90% confidence) for the NDI is 5 points or 10% of points, indicating that although the changes were not statistically significant, they appear to be clinically significant.

The chronic and sub chronic groups followed similar patterns for the total group in pre and post study measures (pre study & post week 4), with significant reductions found in mean pain intensity (VAS) and mean disability (NDI) scores for their pain. The changes in VAS scores for the sub chronic group were significant between pre and post 2 weeks, and pre and post 4 weeks, but not between post 2 and post 4 weeks. While the changes in NDI for the chronic group were also significant between pre and post 2, and pre and post 4 weeks, but not between post 2 and post 4 weeks, similar to the cohort. VAS score changes for the chronic group were seen to be significant between pre and post 2 weeks, and pre and post 4 weeks, but not significant between post 2 and post 4 weeks. Changes in NDI scores for the sub-chronic group were seen to be significant between pre treatment and post 2 weeks, pre and post 4 weeks, yet again were not significant between post 2 and post 4 weeks, despite there being a clear decrease in mean scores.

Although a semi standardised treatment protocol was intended, it must be stressed that osteopathic treatment is always dependent on the clinical findings, and is adjusted to the individual clinical situation. The semi-standardised treatment was used to ensure that the four treating student osteopaths managed their patients in a similar way, and avoided great variances in treatment approach. The main treatments are commonly advocated in osteopathic texts, <sup>14, 19, 20</sup> and the treatment protocol could be varied according to the needs of the patient, and at the discretion of the practitioner, and should enhance the repeatability of the study.

The number of subjects used in the study was relatively small, and a greater number of volunteers would have increased the power of the study to detect significant changes within the sub groups. The duration of the treatment regime was relatively short, especially compared to the mean duration of symptoms (168±292 weeks), but a 4 week trial is likely to be a fair representation of time allocated to a patient before re-assessment in osteopathic practice.

The use of follow-up questionnaires to track patient progress over a longer period of time post treatment is recommended for further studies, as the long-term benefit of osteopathic treatment remains unknown. A control group may have been useful in eliminating the influence of the placebo effect, while also comparing the effects of osteopathic treatment to the natural course of neck pain with no therapeutic intervention. Osteopathic management could be compared to standard medical care or other forms of physical therapy. However, most patients in this study were chronic (mean duration 168.8 weeks) and had a well established pain pattern, so the improvements found in this study suggest strong clinical effects.

A limitation of this study, osteopathically speaking, is that the semi standardised treatment approach did not take into consideration the possibility of underlying biomechanical compensation patterns, arising from remote structures such as the pelvis, or leg length discrepancies for example. Considering the likelihood of neck pain being secondary to dysfunction in remote structures, and the formation of a compensation pattern leading to strains in the neck, treatment of such dysfunctions, if present, may have vielded even more significant results.

#### Conclusion

From this pilot study osteopathic treatment over a 4 week period appeared to be effective in reducing pain, and disability in patients with chronic neck pain. For future research it is recommended that a larger sample size is used, a control group is utilised, and patient progress be monitored over a longer time frame, as this study only examined the effect of osteopathic treatment over a 4 week period, the long term benefit of which still remains unknown.

#### <u>References</u>

- Bovim G, Schrader H, Sand T. Neck pain in the general population. Spine 1994; 19:1207.
- 2. Anderson HI, Ejlertsson G, Leden I, Rosenburg C. *Chronic pain in a geographically defined general population: studies of differences in age, gender, social class, and pain localisation.* Clin J Pain. 1993; 9:174-182.
- Merskey H, Bogduk N. Classification of chronic pain. Descriptions of Chronic pain Syndromes and Definitions of Pain Terms, 2<sup>nd</sup> ed. Seattle: IASP Press, 1994.
- Klenerman L, Slade PD, Stanley I, Pennie B, Reily J, Atchison L, Troup J, Rose M. *The prediction of chronicity in patients with an acute attack of low back pain in a general practice*. Spine 1995; 20 (4) 478-84
- Moseley GL. *The incidence of injury in surfboat rowers*. Australian Journal of Science and Medicine in Sport. 1995; 26 (4) 97-104.
- Bogduk N. *The physiology of deep somatic pain*. Journal of Australasian musculoskeletal medicine 2002 May; 2; 307-312
- Bruckner, Peter Khan, Karim. *Clinical Sports Medicine*. Mc Graw Hill 2004: 215-18, 227

- Kappler RE, *Cervical Spine* Chap 46 Foundations of Osteopathic medicine
  2<sup>nd</sup> ed. Philadelphia: Lippincott Williams & Wilkins. 2002
- Hoving JL, Koes BW, de Vet HC, van der Windt DA, Assendelft WJ et al. Manual Therapy, Physical Therapy, or Continued Care by a General Practitioner for Patients with Neck Pain: A Randomized, Controlled Trial. Ann Intern Med. 2002.
- 10. Pikula, JR The effect of spinal manipulative therapy (SMT) on pain reduction and range of motion in patients with acute unilateral neck pain: a pilot study, The Journal of the Canadian Chiropractic Association.1999 June:43
- Jordan A, Bendix T, Nielsen H, Hansen FR, Host D, Winkel A. Intensive training, physiotherapy, or manipulation for patients with chronic neck pain. A prospective, single blinded, randomised clinical trial. Spine. 1998; 23:311-9.
- 12. Bronfort G, Evans R, Nelson B, Aker PD, Goldsmith CH, Vernon H. *A* randomised clinical trial of exercise and spinal manipulation for patients with chronic neck pain. Spine. 2001;26(7):788-97.
- Ingeborg B C Korthals-de Bos, Cost effectiveness of physiotherapy, manual therapy, and general practitioner care for neck pain: economic evaluation alongside a randomised controlled trial, BMJ 2003. 326 (7395): 911.
- Greenman, P. Principles of Manual Medicine, Limmincott Williams & Wilkons 1996.

- Patrick D. Wall, Ronald Melzack, *Textbook of pain 4th ed*. Edinburgh : Churchill Livingstone, 1999
- Vernon H, Mior S. *The Neck Disability Index: a study of reliability and validity*. Journal of Manipulative and Physiological Therapeutics 1991 Sep;14(7):409-15.
- 17. Bolton J, Wilkinson R. Responsiveness of pain scales: A comparison of three pain intensity measures in chiropractic patients. Journal of Manipulative and Physiological Therapeutics. 1998 Jan;21(1):1-7
- 18. Lorig, Kate. *Outcome measures for health education and other health and other health care interventions*. Thousand Oaks: Sage Publications, 1996.
- Gibbons P, Tehan P. Manipulation of the spine, thorax and pelvis, London: Churchill livingstone 2000
- 20. Ward RC. Foundations for Osteopathic medicine 2<sup>nd</sup> ed. Philadelphia:
  Lippincott Williams & Wilkins. 2002
- 21. Price DD, McGrath PA, Rafii A, Buckingham B. *The validation of visual analogue scales as ratio scale measures for chronic and experimental pain.* 1983 Sep;17(1):45-56.

## Appendix

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Appendix Appendix 1 : Raw data of the cohort									
Subject No	Age	Sex	DOS	VAS1	VAS2	VAS3	NDI1	NDI2	NDI3
1	42	М	4	0.4	0.1	0.05	10	10	10
2	40	F	6	9.6	0.7	0.5	46	22	20
6	22	F	52	2.4	1.3	0.9	10	6	6
7	23	М	20	1.7	0.3	0.4	8	4	0
8	44	М	24	6.7	4.8	5.5	11.11	4.44	17.77
13	37	F	32	5.3	0.9	0.2	18	12	0
14	20	М	20	8.6	3	3.2	6	4	12
15	50	F	52	8.7	4.7	Х	46	46	X
17	21	F	12	9.2	4.2	Х	22	22	X
21	37	М	16	7.6	3.1	1	38	26	0
9	27	F	208	8.8	0.6	0.4	28	6	12
10	22	F	260	7.4	2	Х	30	24	X
11	58	F	1040	7.4	1.3	0.2	30	16	0
12	38	F	104	7.9	1	Х	16	18	X
16	24	М	136	8.6	3.7	0.5	16	0	0
19	36	М	780	1.4	0.7	0.2	26.66	20	17.77
20	51	F	104	9.3	7.6	6	38	26	0
Mean	34.823		168.82	6.521	2.352	1.465	22.81	15.08	8.58

		3						
SD		292.05						
	11.912	3	3.092	2.081	2.068	12.61	11.38	7.93

\*missing data for VAS3 were replaced with series means to the value of 1.47

\*missing data for NDI3 were replaced with series means to the value of 8.58

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## Appendix 2: Raw data of the Sub-chronic and Chronic groups

Subject						
No	Age	Gender	Duration Sx Weeks	Baseline NDI score (value)	baseline %	NDI 2
			sub chronic			
1	42	М	4	5	10	5
2	40	F	6	23	46	11
6	22	F	52	5	10	3
7	23	М	20	4	8	2
8	44	М	24	5 - 45 questions answered	11.11	2
13	37	F	32	9	18	6
14	20	М	20	3	6	2
15	50	F	52	23	46	23
17	21	F	12	11	22	11
21	37	Μ	16	19	38	13

Mean			23.8		21.511	
SD	11.06747		16.98234377		15.9171497	
			chronic			
9	27	F	208	14	28	3
10	22	F	260	15	30	12

44	50	г	1040	15	20	0
11	00	Г	1040	10		0
12	38	F	104	8	16	9
16	24	Μ	136	8	16	0
19	36	М	780	12 - 45 questions answered	26.66	9
20	51	F	104	19	38	13
Mean	36.57143		376		26.38	
SD	13.73386		376.6873151		7.952198857	

					+			
				N	C			
				N				
Appendix 3: VAS Output - Cohort								
				) .				
Mauchly's Test of	of Spheric	city						
Measure: MEAS	URE_1							
Ma	uchly's	Approx.	df	Sig.	Epsilon			
	W	Chi-						
		Square						
Within				~	Greenhou	Huynh-	Lower-	
Subjects					se-Geisser	Feldt	bound	
Effect		×	$\mathbf{O}^{*}$					
TIME	.666	6.097	2	.047	.750	.810	.500	
Tests the null hy	Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed							
dependent varia	bles is pr	oportional to a	n identity	matrix.				

a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept Within Subjects Design: TIME

Tests of Within-Subjects Effects

Measure: MEASURE_1								
Source	Type III Sum of	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
	Squares		•			•		
TIME Sphericity Assumed	246.472	2	123.236	36.007	.000	.692	72.015	1.000
Greenhou se-Geisser	246.472	1.499	164.399	36.007	.000	.692	53.983	1.000
Huynh- Feldt	246.472	1.620	152.171	36.007	.000	.692	58.321	1.000
Lower- bound	246.472	1.000	246.472	36.007	.000	.692	36.007	1.000

Error(TIM Sphericity	109.521	32	3.423
E) Assumed Greenhou	109.521	23.988	4.566
se-Geisser Huynh-	109.521	25.915	4.226
Feldt Lower-	109.521	16.000	6.845
bound			

a Computed using alpha = .05

Paired Samples Test E	Paired Difference S Mean Std. Deviation	Std. Error Mean C	95% onfidenc e Interval of the		t	df	Sig. (2- tailed)
			Difference	Linner			
Pair 1 VAS1	4 1176 2 56035	62316	2 7066	Upper 5 / 387	6 608	16	000
VAS2	4.1170 2.30933	.02310	2.7900	5.4507	0.000	10	.000
Pair 2 VAS1 - SMEAN(V	5.0640 3.22278	.78164	3.4070	6.7210	6.479	16	.000
Pair 3 VAS2 - SMEAN(V AS3)	.9464 1.88342	.45680	0220	1.9147	2.072	16	.055

# Appendix 4: VAS Output – Chronic Group

Mauchly's T	est of Spheri	city					
Measure: M	EASURE_1						
	Mauchly's W	Approx. Chi- Square	df	Sig.	Epsilon		
Within Subjects Effect				Gr se	eenhou Geisser	Huynh- Feldt	Lower- bound
TIME	.460	3.878	2	.144	.650	.754	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept Within Subjects Design: TIME

					•	$\mathcal{A}$			
	ithin Outline	ta ⊑∰a ata		A	C				
Measure: N	IIIIIII-SUDJEC	is Enecis		$\sim$	S.				
Source	, ,	Type III Sum of	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
TIME	Sphericity Assumed	Squares 135.265	<b>C</b> 2	67.633	25.706	.000	.811	51.413	1.000
	Greenhou	135.265	1.299	104.126	25.706	.001	.811	33.394	.997
	Huynh-	135.265	1.509	89.643	25.706	.000	.811	38.789	.999
	Lower-	135.265	1.000	135.265	25.706	.002	.811	25.706	.986
Error(TIM	Sphericity	31.572	12	2.631					
L,	Greenhou	31.572	7.794	4.051					
	Huynh- Feldi	31.572	9.054	3.487					
	Lower-	31.572	6.000	5.262					
a Compute	ed using alp	ha = .05							
Paired San	nples Test	Datast							0
		Difference					t	đĩ	tailed)
		s Mean	Std. Deviation	Std. Error Mean (	95% Confidenc e Interval				

				I	of the Difference Lower	Upper			
Pair 1	PRE - POST2	4.8429	2.72143	1.02860	2.3260	7.3598	4.708	6	.003
Pair 2	PRE - SMEAN(P OST4)	5.7971	2.64100	.99820	3.3546	8.2397	5.808	6	.001
Pair 3	POST2 - SMEAN(P OST4)	.9543	1.18523	.44797	1419	2.0504	2.130	6	.077

Appendix 5: VAS Output – Sub-Chronic Group

Mauchlv's T	est of Spheri	citv 🔷					
Measure: M	EASURE_1		μt	Pin	Faciloa		
	Wauchiys	Chi-		oiy.	Epsilon		
		Square					
Within			$\sim$		Greenhou	Huynh-	Lower-
Subjects		X	)		se-Geisser	Feldt	bound
Effect TIME	.395	7.436	2	.024	.623	.674	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept Within Subjects Design: TIME

#### Tests of Within-Subjects Effects Measure: MEASURE 1

6

Source	Type III Sum of	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
	Squares							
TIME Sphericity	117.286	2	58.643	18.755	.000	.676	37.511	.999
Assumed	447 000	4 0 4 0	04407		004	070	~~~~~	
Greenhou se-Geisser	117.286	1.246	94.137	18.755	.001	.676	23.368	.988
Huynh- Feldt	117.286	1.349	86.953	18.755	.000	.676	25.298	.992
	447 000	4 000	447.000	40 755	000	070	40 755	070
Lower-	117.286	1.000	117.280	10.755	.002	.676	10.755	.970

bound			
Error(TIM Sphericity	56.281	18	3.127
E) Assumed			
Greenhou	56.281	11.213	5.019
se-Geisser			
Huynh-	56.281	12.140	4.636
Feldt			
Lower-	56.281	9.000	6.253
bound			

a Computed using alpha = .05

Paired Samp	oles Test	Paired Difference s Mean	Std. Deviation	Std. Error Mean C	95% onfidenc e Interval of the Difference		t	df	Sig. (2- tailed)
Pair 1	PRE -	3,7100	2.59077	.81927	Lower 1.8567	Upper 5,5633	4.528	9	.001
i un i	POST2		2.00011	.01021		0.0000		U	
Pair 2 S	PRE - MEAN(P OST4)	4.5513	3.19665	1.01087	2.2645	6.8380	4.502	9	.001
Pair 3	POST2 - SMEAN(P OST4)	.8413	1.35262	.42774	1264	1.8089	1.967	9	.081

## Appendix 6: NDI Output – Cohort

Mauchly's Test of Sph	ericity					
Measure: MEASURE	1					
Mauchly	s Approx.	df	Sig.	Epsilon		
V	V Chi-		-			
	Square					
Within			G	reenhou	Huynh-	Lower-

Subjects				Se	e-Geisser	Feldt	bound
Effect							
TIME	.731	4.707	2	.095	.788	.859	.500
Tests the null	hypothesis	that the error	covariance	matrix of	the orthonori	malized tra	nsformed

dependent variables is proportional to an identity matrix. a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept Within Subjects Design: TIME

				•×	4			
			A	5				
Tests of Within-Subject	s Effects		$\mathcal{O}$	101				
Source	Type III Sum of	df	Mean Square	F	Sig. I	Partial Eta Squared	Noncent. Parameter	Observed Power
TIME Sphericity	Squares 1725.411	C <sub>2</sub>	862.705	14.629	.000	.478	29.257	.998
Assumed Greenhou	1725.411	1.576	1095.079	14.629	.000	.478	23.049	.991
se-Geisser Huynh-	1725.411	1.718	1004.145	14.629	.000	.478	25.136	.994
Feldt Lower-	1725.411	1.000	1725.411	14.629	.001	.478	14.629	.948
Error(TIM Sphericity E) Assumed	1887.174	32	58.974					
Greenhou se-Geisser	1887.174	25.210	74.859					
Huynh- Feldt	1887.174	27.493	68.643					
Lower- bound	1887.174	16.000	117.948					
a Computed using alph	a = .05							
Paired Samples Test								
	Paired Difference					t	df	Sig. (2- tailed)
	s Mean	Std. Deviation	Std. Error Mean C	95% Confidenc e Interval				

					of the Difference Lower	Upper			
Pair 1	NDI1 - NDI2	7.7253	7.67415	1.86126	3.7796	11.6710	4.151	16	.001
Pair 2 SM	NDI1 - EAN(N DI3)	14.2300	12.70552	3.08154	7.6974	20.7626	4.618	16	.000
Pair 3 SM	NDI2 - EAN(N DI3)	6.5047	11.55519	2.80254	.5636	12.4458	2.321	16	.034

Appendix 7: NDI Out	put - Chronic Group
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Appendix '	7: NDI Out	tput - Chronic	Grou		, lere	tes,	
Mauchly's Te Measure: ME	est of Spheri EASURE_1 Mauchly's W	city Approx. Chi-	df	Sig.	Epsilon		
Within Subjects Effect	00.4	Square			Greenhou se-Geisser	Huynh- Feldt	Lower- bound
TIME	.834	.906	2	.636	.858	1.000	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept Within Subjects Design: TIME

#### Tests of Within-Subjects Effects Measure: MEASURE 1

Source	Type III	df	Mean	F	Sia	Partial Eta	Noncent	Observed
Obuloc	Sum of	u	Square		Olg.	Squared	Parameter	Power
	Squares		Oquare			Oqualca		1 Ower
TIME Sphericity	1461.232	2	730.616	14.306	.001	.705	28.612	.991
Assumed								
Greenhou	1461.232	1.716	851.687	14.306	.001	.705	24.544	.981
se-Geisser								
Huynh-	1461.232	2.000	730.616	14.306	.001	.705	28.612	.991
Feldt								
Lower-	1461.232	1.000	1461.232	14.306	.009	.705	14.306	.880

	bound			
Error(TIM	Sphericity	612.854	12	51.071
E)	Assumed			
	Greenhou	612.854	10.294	59.534
	se-Geisser			
	Huynh-	612.854	12.000	51.071
	Feldt			
	Lower-	612.854	6.000	102.142
	bound			

a Computed using alpha = .05

Paired Samples Test D	Paired ofference s Mean	Std. veviation	Std. Error Mean C	95% Confidenc e Interval of the Difference L ower	Upper	t	df	Sig. (2- tailed)
Pair 1 NDIPRE -	10.6657	7.83213	2.96027	3.4222	17.9092	3.603	6	.011
NDIZ Pair 2 NDIPRE - SMEAN(N DI4)	20.4260 1	0.75185	4.06382	10.4822	30.3698	5.026	6	.002
Pair 3 NDI2 - SMEAN(N DI4)	9.7603 1	1.37904	4.30087	7636	20.2841	2.269	6	.064

# Appendix 8 - NDI Output – Sub-Chronic Group

Mauchly's T	est of Spheric	city					
Measure: M	EASURE_1						
	Mauchly's	Approx.	df	Sig.	Epsilon		
	Ŵ	Chi-		•			
		Square					
Within				G	Freenhou	Huynh-	Lower-
Subjects Effect				S	e-Geisser	Feldt	bound
LIICOL							

TIME .485 5.793 2 .055 .660 .729 .500 Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept Within Subjects Design: TIME

				• X	1	
				S		
Tests of Within-Subjects	s Effects		0	101		
Measure: MEASURE_1		<b>O</b>			<u>.</u>	
Source	I ype III Sum of	dt	Mean	F	Sig. Pa	rtial Eta
	Squares	c	Square		Ċ	squareu
TIME Sphericity	887.121	2	443.561	4.701	.023	.343
Assumed	887 121	1 320	672 108	4 701	043	343
se-Geisser	007.121	1.020	072.100	4.701	.040	.0-0
Huynh-	887.121	1.458	608.368	4.701	.038	.343
Feldt	007 101	1 000	007 404	4 704	050	242
Lower-	887.121	1.000	887.121	4.701	.058	.343
Error(TIM Sphericity	1698.449	18	94.358			
E) Assumed						
Greenhou	1698.449	11.879	142.977			
se-Geisser Huvnh-	1698 449	13 124	129 418			
Feldt	1000.440	10.124	120.410			
Lower-	1698.449	9.000	188.717			
bound						
Paired Samples Test						
r	Paired					t
L	superence					
	Mean	Std.	Std. Error	95%		
		Deviation	MeanCo	onfidenc		
				e Interval		

df

Sig. (2tailed)

				I	of the Difference Lower	Upper			
Pair 1 NDI	PRE - NDI2	5.8670	7.39573	2.33874	.5764	11.1576	2.509	9	.033
Pair 2 NDI SME	PRE - AN(N DI4)	13.2898	16.51689	5.22310	1.4743	25.1052	2.544	9	.031
Pair 3 I SME	NDI2 - AN(N DI4)	7.4228	15.44814	4.88513	-3.6282	18.4737	1.519	9	.163

#### **Appendix 9: Effect size calculations (Cohen's d)**

#### VAS cohort

Appendix 10: Information to Participants Form

#### **INFORMATION TO PARTICIPANTS:**

#### THE EFFECT OF OSTEOPATHIC TREATMENT ON PATIENTS WITH PERCEIVED SUBACUTE NECK PAIN

#### Aim of the study:

To examine the effect of Osteopathic treatment on self-reported pain and disability measures in patients suffering from sub-acute neck pain

#### Inclusion criteria

Participants with intermittent or constant neck pain for a duration longer than a month.

*Exclusion criteria* 

Participants will be excluded if they have suffered constant unremitting neck pain for greater than six months, have any neurological signs and symptoms, suffer from cervical intervertebral disc prolapse and trauma such as whiplash. (Note the unremitting is defined as a pain that is always present.) Volunteers currently receiving regular manual therapy will also be excluded.

Participants will be informed of the study design via an information sheet, and will sign a consent form prior to involvement

#### Procedures

Participants who meet the selection criteria will be offered a six-week treatment plan at the Victoria University Osteopathic Medicine Clinic, and will be asked to sign a consent form.

One week prior, and again on the initial visit, participants will be requested to fill out a McGill pain scale questionnaire (in which they will be presented with 80 adjectives in groups, and have to select one from each group that most closely matches their own pain. The words are given a numerical scale rating in relation to the mildest to the worst. This will determine the pain rating index.) A Neck Disability Index (NDI), will also be completed (Similar to the Mc Gill Questionnaire, the NDI asks questions that concern impairments such as pain (including headaches), and abilities to perform tasks like personal care, lifting, reading, driving, and recreation to indicate participants' perceived pain. These two pre-treatment questionnaires will establish the pre-treatment baselines. The result of these questionnaires will be compared with subsequent post treatment evaluations.

The first consultation of the trial will replicate an initial consultation for any new patient presenting to the Osteopathic Medicine Clinic (OMC). The practitioner will be a senior student (5<sup>th</sup> year) who will undertake the treatment under the supervision of a registered Osteopath. Participants will be treated as typical osteopathic patients.

A 1-hour initial consultation will include a thorough medical case history and an osteopathic examination, which includes assessment of symmetry in the body, ranges of motion in various joint systems throughout the body (primarily the neck, upper thoracic spine and chest in this case,) tissue texture changes (eg. tight muscles,) and screening for abnormal tenderness.

A semi-standardised treatment protocol will include the following elements:

6. Soft Tissue Technique to trapezius, cervical/thoracic erector spinae, levator scapulae, and sub occipital muscles (All muscular structures around the neck and upper back). Soft tissue technique is a massage-based technique whereby the

practitioner aims to release tension and improve circulation in the affected musculature to assist healing.

- 7. Articulation Technique (passive mobilisation) to the neck and upper/mid back). Articulation technique involves the passive movement of a restricted joint through its ranges of motion to restore normal function within the joint.
- 8. Muscle energy technique to the scalenes, levator scapulae, trapezius, SCM muscles (muscles in the neck). Muscle energy technique involves the practitioner taking up a barrier in a restricted joint/muscle, and the participant performing a light isometric contraction against the practitioner's resistance for a short time before relaxing again, enabling the surrounding musculature to undergo a phenomena known as post isometric relaxation, and hence improving the mobility of said joint/muscle.
- 9. Counterstrain Technique where appropriate. Counterstrain is an indirect technique whereby the practitioner uses passive movement of a restricted joint/muscle to put it into a position of ease, in effect resetting a neural feedback loop from said muscle /joint to brain. This technique has the effect of being able to release tension and hypertonicity.
- 10. HVLA (mobilisation with Impulse) to the cervical and thoracic vertebrae if indicated. HVLA (High Velocity Low Amplitude) technique is a method employed by many health care practitioners in which a restricted joint is taken to its end range of restriction, and with a gentle thrust technique, taken past that barrier back to its normal range. An audible click or pop may be heard, which is the normal sign of successful HVLA.

All the techniques in the treatment protocol are considered standard by the osteopathic profession.

Many of the individual techniques have been previously approved by the VU Human Research Ethics Committee.

Participants will be requested to undertake osteopathic treatment twice a week for two weeks, and once a week for the following four weeks. The McGill pain scale and Neck Disability Index will be completed prior to the initial treatment and the end of weeks 2, 4 and 6.

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