Osteopathic Treatment to Patients with Primary Dysmenorrhea

Principal Investigator: Rosette Pirritano BSc – Clinical Science

Principal Supervisor: Dr. Brian Nicholls D.O, M.A.

Secondary Supervisor: Dr. Jim Kiatos MB.BS.ND

Correspondance: Brian Nicholls

Department of Health Sciences

Faculty of Human Development

Victoria University

PO Box 14428 MCMC

Melbourne 8001

Australia

E-mail: Brian.Nicholls@vu.edu.au

Phone: 92481150

ABSTRACT

Objective: To study whether the pain associated with primary dysmenorrhea as well as the amount of medication used can be reduced via the application of osteopathic techniques including muscle energy technique, high velocity low amplitude technique and visceral manipulation.

Subjects: Twenty (N=20) female participants aged between 18 and 25 were recruited into the study via notices displayed around the Victoria University teaching clinic.

Design: Participants were randomly allocated to either an experimental group or control group. Baseline menstrual pain scores were obtained from both groups using the Mankoski pain scale. The control group rated their pain for three cycles without receiving any treatment. The experimental group received one treatment per cycle for three cycles between days 8-10 of their menstrual cycle. The Mankoski pain scale was used to rate the pain experienced each cycle. Medication diaries were kept by both groups.

Setting: Victoria University osteopathic teaching clinic

Data analysis: Data was analysed via a SPANOVA using baseline data as covariates. Further analysis was performed using an ANOVA. Significance levels were set at $P < .05$. Power and eta squared were observed. Medication use in each cycle was analysed using graphs created with MS Excel. The graphs looked at the type of medication taken, when it was taken and the amount.

Results: Pain scores consistently decreased in the experimental group with time when compared to the baseline scores and the control group ($p < .05$). The same trend was consistently seen in relation to medication use. An observed power of 1.000 was obtained.

Conclusions: Within the limitations of the study, the results support the hypothesis that osteopathic treatment can decrease the pain associated with primary dysmenorrhea as well as the amount of medication taken. The results of this study present valuable outcomes for women with primary dysmenorrhea and Osteopaths wishing to provide relief to such patients. However, further research is needed to establish whether or not the benefits are lasting

Key Indexing Terms: Dysmenorrhea, osteopathy, pain, medication, outcomes.

INTRODUCTION

Dysmenorrhea comes in two forms, primary (functional) and secondary (acquired).[1] Primary dysmenorrhea (PD) can be defined as abdominal and or back pain associated with the ovarian cycle in the absence of an organic pelvic pathology such as endometriosis or polyps.[1, 2, 3] When there is presence of a pelvic pathology such as endometriosis or polyps it is referred to as secondary dysmenorrhea.[1, 2, 3] Up to 50% of women of childbearing age are affected by PD, with 10% being affected so severely that they are unable to perform daily living activities for 1-3 days at the commencement of menstruation.[2] Severe sufferers of PD cost the workforce billions of dollars due to absenteeism leading to lost hours.[2] PD may begin at puberty and may continue until pregnancy and even later. The symptoms and signs that are typical of PD include lower abdominal pain that involves cramp-like episodes (spasmodic dysmenorrhea) or dull constant pain (congestive dysmenorrhea).[4] The pain may also be in the lower back and radiate down the legs.[4] Non-steroidal anti-inflammatory drugs are the commonest choice of treatment.[5]

Pathophysiology of primary dysmenorrhea

Although the precise aetiology is unknown some suggestions have accumulated which attempt to explain the predisposition for PD. During the monthly ovarian cycle many hormones are produced.[6] When prostaglandins, released by the endometrium, increase, they cause increased uterine smooth muscle contraction and vasospasm of the uterine arterioles.[6] This may lead to the cramp like pain that is PD.[2]

Other suggestions include imbalance of the estrogen-progesterone ratio, positional

changes of the uterus, poor posture or somatic imbalances, especially around the lower thoracic, lumbar and pelvic regions and weakened pelvic and abdominal tone leading to decreased support and irritability of the uterus due to interruption in its nerve supply.[7]

Orthodox treatment of primary dysmenorrhea

Current treatment of PD is mainly via non-steroidal anti-inflammatory drugs (NSAIDS) such as naproxen (e.g. Naprogesic), ibuprofen (e.g. Nurofen) and mefenamic acid (e.g. Ponstan). [5] The oral contraceptive pill (OCP) has also been used as treatment. [2] However unwanted side effects have been shown to be present with the current treatments. [5] Some of the more common side effects of NSAIDS include gastric irritation, diarrhea, gut disturbances, nausea, headaches and dizziness. Other side effects can include gastric ulcers, gut bleeds, impaired renal function, provocation of allergic reactions, skin rashes, blood disorders and/or long-term acceleration of joint destruction in arthritic conditions.[8, 9]

Side effects of the OCP include a four-fold increase in the risk of thromboemboli in high-risk women (ie. those with a family history of heart disease, hypertension, smokers etc). Headaches, fluid retention, breast tenderness, mood changes, impaired lactation, acne, thrush, irregular and prolonged bleeding, an increased risk of cervical cancer, a possible increased risk of breast cancer, an increased risk of stroke and myocardial infarction are other possible side effects.[8, 9]

Therefore exploration of other treatments such as manual therapy is desirable so as to reduce the risks involved with drugs and treat the source of pain rather than the symptoms.

Palpation/physical findings in patients with primary dysmenorrhea

Nichols [10] conducted a pilot study that looked at osteopathic examination findings in 20 women with primary dysmenorrhea. The areas that were looked at were the thoracic, lumbar, abdominal and pelvic regions. Osteopathic screening techniques were used. The aim of the study was to see if there were common somatic dysfunction findings among sufferers of dysmenorrhea. The results indicated a number of common areas with somatic dysfunction. Somatic dysfunction can be defined as "impaired or altered function of related components of the somatic (body framework) system; skeletal, arthroidal and myofascial structures; and related vascular, lymphatic and neural elements" [11]. There are four diagnostic criteria to assess somatic dysfunction [11]:

1. Asymmetry: Asymmetry of the musculoskeletal system, either functional or structural.
2. Range of motion: Range of motion abnormalities of the joints of the skeletal system. This may be seen in restriction of movements or hypermobility. It can be tested using active and passive movements.
3. Tissue texture abnormality: Alterations of the soft tissues of the musculoskeletal system (skin, fascia, muscle, ligament). This can be assessed via observation, palpation and percussion.
4. Tenderness: Tenderness on palpation may be another indication of somatic dysfunction.

Nichols[10] found that somatic dysfunction was present in the innominates, sacrum, lumbar erector spinae, iliac region and suprapubic region in 100 per cent of subjects. 95 per cent

of participants had somatic dysfunction in the diaphragm and inguinal ligament region. 90 per cent of participants had somatic dysfunction in the quadratus lamborum muscle and L3. 61 per cent had spinal somatic dysfunction at one or more levels at T10, 11,10, L1, 2. The study concluded that there are structural dysfunctional similarities in sufferers of primary dysmenorrhea, which may contribute to the cause, and or exacerbation of pain. The study did not however compare non-sufferers of PD for somatic dysfunction.

The areas that were examined specifically in the present study were the thoracic, lumbar, abdominal and pelvic regions. They were treated as seen appropriate by the researchers. Specifically the techniques that were used included spinal manipulation, muscle energy techniques and soft tissue release.

MANUAL THERAPY FOR TREATMENT OF PRIMARY DYSMENORRHEA

Muscle Energy Technique

Muscle energy technique (MET) is a technique whereby the patient actively uses their muscles against a counterforce produced by the practitioner. [11] The practitioner controls the intensity, timing and direction.[11] According to Greenman, [11] MET can be used to "lengthen a shortened, contractured or spastic muscle; to strengthen a physiologically weakened muscle or group of muscles; to reduce localized oedema and relieve passive congestion (the muscles are the pump of the lymphatic and venous systems); and to mobilize an articulation with restricted mobility".

Thus far there has not been any studies that have only focused on the use of MET as a technique choice for the treatment of PD, however there have been studies that have incorporated MET. This is discussed later.

Soft tissue techniques

Soft tissue techniques are believed to have mechanical, circulatory and neurological effects. They can enhance venous and lymphatic return, decongest parts of the body and reduce hypertonicity and spasm. [11] There has not been any studies that have focused exclusively on soft tissue but again have incorporated it into their research. Again this will be discussed later.

Spinal Manipulation

Spinal manipulation is a technique used by many osteopaths. Osteopaths believe that spinal manipulation (i.e. a technique whereby the spine is placed into a locked position and a high velocity low amplitude force is put through a specific segment of the spine) induces a somatovisceral reflex.[11] A somatovisceral reflex may occur when the soft tissue surrounding a vertebral segment (somatic) is manipulated causing visceral activity such as abdominal cramping to be influenced. [12] The abdominal cramping is though to occur via neural relationships; autonomic fibers from skeletal muscle in the dorsolumbar area, or via craniosacral (parasympathetic) supply through facilitation of the sacral nerves.[7,13] In particular it has been suggested that spinal dysfunction, especially in the lower back could cause abnormal nerve impulses to organs such as the uterus, which may then influence its function causing pain.[7,14]

Spinal manipulation is also thought to causes the beta-endorphin plasma level to be elevated. According to Vernon,[10] "beta-endorphin has been found to produce a wide range of beneficial effects, especially analgesia".

The vertebral levels associated with the sensory and motor neural supply to the uterus and reproductive system are from the 10th thoracic to the 5th lumbar and 1st sacral vertebra (T10 – L5-S1) and the sacroiliac joint. [2] This coincides with the results obtained by Nichols[10] that found areas of somatic dysfunction in the related areas of nerve supply. Vernon et al. [12] conducted a study that examined the effect of spinal manipulation on the release of beta-endorphins. Blood samples were taken 15and 5 min pre-intervention and 5, 15 and 30 min post- intervention from twenty-seven male subjects and compared. They found that there was a small but statistically significant elevation of plasma beta-endorphin levels, which may show that spinal manipulation, as used in this study, can be used as a technique that may induce an analgesic effect.

In an eight-month study Kokjohn et al.[2] compared spinal manipulation to a sham procedure involving forty-five subjects. The treatment consisted of a high-velocity, short lever, low-amplitude thrust delivered to vertebral levels within T10 and L5-S1 and the sacroiliac joints. These areas were chosen due to their relationship with the nerve supply to the area of the uterus. The participants were treated on the first day of their menstrual cycle. A visual analogue scale and menstrual distress questionnaire were used to measure pain 15 min before treatment and 60 min post- treatment. Compared to the sham group,

they found that over time there was a decrease in pain perception in the experimental group.

The results obtained by Walsh et al. [15] demonstrated that spinal manipulation is effective in reducing symptoms associated with premenstrual syndrome. Eight subjects took part in the study, which involved spinal manipulation and soft tissue techniques. An average of 3 treatments were given over a 10-day period before the start of menses (the exact dates were not given). This continued for 3 cycles. Although the group showed a reduction in pain ($p < 0.05$), a definitive conclusion cannot be drawn due to the small number of subjects and lack of controls.

In a study conducted by Proctor et al.[16] spinal manipulative therapy was tested against a sham treatment for its effectiveness in reducing pain associated with primary and secondary dysmenorrhea. The results of the study suggested that SMT was no more effective than the sham manipulation for the treatment of dysmenorrhea. The poor results from this study, compared to others, may be due to the inclusion of secondary dysmenorrhea patients.

Visceral Techniques

Visceral techniques are commonly used in treatment by some Osteopaths. [14] They work directly on the organs and surrounding structures in order to enhance the circulation of fluid and visceral motion as well as having other benefits.[14] According to Barral and Mercier, [14] visceral manipulation is believed to affect mobility and motility, circulation of

fluids, sphincter and muscular spasms, hormonal and chemical production, immunity (both localized and systemic), and the psyche.[14] Dysfunction of the uterus, such as increased contractility, is thought to be a major cause of dysmenorrhea, inducing a viscerosomatic reflex. This may present as abnormal rigidity of the paravertebral musculature or a reduction of spinal movement especially in the lower thoracic and upper lumbar region. [7,13]

Organs are able to slide and glide within the body due to ligaments that support and guide them.[13] If movement is restricted then the organ cannot function as normal leading to dysfunction.[13] Visceral (osteopathic) treatment works directly on the organs and surrounding structures and aims to enhance the circulation of fluid and visceral motion.[13, 14] Nielsen[13] performed a pilot study investigating the effect of visceral treatment only on patients with primary dysmenorrhea. The aim was to decrease pain and analgesic usage for young women. This allowed the patients to take medication if they needed. Six participants took place in the study and a baseline pain value was measured over one cycle prior to treatment. Treatment was performed for another two cycles (1 treatment per cycle) between days 8 and 10 of their cycle. Mankoski pain questionnaires were filled out and a medication diary was kept. The results suggested that there was a significant decrease in pain experienced from baseline to cycle 3 ($p < 0.05$) with a power of 1.000 (alpha = 0.05). Medication use was measured with graphs and also showed a significant decrease. Despite a significant decrease in pain and analgesic use the study did not have a placebo or control group making it difficult to confirm that the treatment was effective, especially with only six participants.

Combination of Techniques

Chadwick and Morgan [17] used a variety of techniques quite similar to those used in this study (MET, HVLA, soft tissue, visceral) however they also used cranial techniques. The study was conducted over four cycles using six treatments. A modified McGill pain questionnaire was used to analyse pain. Their study found that there was a decrease in pain experienced ($P<.05$), however they attributed this mainly to manipulation but did not discount the need to decrease the viscero-somatic reflex causing hyper- excitability of the visceral organs such as the uterus via visceral techniques. They also concluded that an incorporation of techniques (MET, soft tissue) may give a longer lasting effect.

The aim of this study was to investigate the effectiveness of osteopathic treatment on patients with primary dysmenorrhea. Specifically the treatment aimed to decrease the pain associated with primary dysmenorrhea and the amount of medication used. Previous studies may have used similar techniques to those used in this study, however they were administered at different stages on the menstrual cycle. One study administered treatment at the same time as this study however the same techniques were not used. A study of this exact nature has not as yet been undertaken and adds to the research available.

MATERIALS AND METHODS

Subjects

Twenty (N = 20) women aged between 18 and 30 (mean 23 years) with a history of primary dysmenorrhea participated in the study. Twenty- two participants were recruited into the study however two participants were excluded from the study as they both had a history [BRV1]. of endometriosis Participants were recruited into the study via notices displayed in the student osteopathic teaching clinic at Victoria University. Before beginning the study the participants completed and signed a consent form. Once consent had been granted, R. P (student osteopath) took a full medical, gyneacological and menstrual history in a clinic room. This was to determine that the source of pain was most likely due to primary dysmenorrhea and ensure that it was safe to perform the relevant treatment on the participant.

Inclusion criteria

The criteria for inclusion and exclusion into the study were equivalent to those of Kokjohn et al. [2] and were as follows:

1. Onset of primary dysmenorrhea within 2 years of menarche.
2. Menstrual pain beginning the day before or just after the onset of menstrual flow.
3. Menstrual pain experienced each cycle and scored as a 3 or higher on the Mankoski pain questionnaire. A score of 3 is seen as neutral on the pain questionnaire.
4. Regular cycles (within +/- 3 days).

Exclusion criteria

Participants were excluded from the study if:

1. Primary dysmenorrhea was found not to be the cause of pain after questionnaires were filled out. E.g. the participant had been diagnosed with polyps of the uterus.
2. There was a history of endometriosis.
3. There was presence of contraindications to high velocity low amplitude thrust (HVLA) technique such as bone pathology or fracture.
4. The participant was over the age of thirty or under the age of eighteen. This was so there was not too great a difference in age and so that ethical approval could be obtained.
5. History of pregnancy so as to avoid influencing factors involved with the pregnancy.

Procedure

Before beginning the treatment, participants rated their pain using the Mankoski pain questionnaire (Appendix 1) at the time at which they had pain. The Mankoski pain questionnaire is a pain scale created by Andrea Mankoski and is based on the ability to function. It is similar to the numerical scale used by Liebel & Butler[18] and was based on Andrea Mankoski's experience with severe chronic pain from endometriosis. This pain scale is currently also used by an emergency response team in Colorado and in a burns centre in Canada, and many other health groups. It was used in research (unpublished)

done by the Occupational Therapy department of the college of Miscericordia in the US.[19] It is currently being used in research into the sociology of pain. The pain scale is also published in the *Patient Education in Primary Care* newsletter which is allied with the US department of veterans affairs.[20] Nielsen[13] recently used this questionnaire in a similar unpublished study. A Baseline score was collected from each of the participants. This score was used to compare pre- and post- treatment results.

The participants were then randomly allocated into two groups via coin toss, (i.e. group A – control group, group B – intervention group) each with an equal number of participants. The control group did not receive any treatment but were encouraged to continue taking their medication as needed. The inclusion and exclusion criteria also applied to the control group. The intervention group was able to be compared to the control group to see if treatment was better than no treatment. They were asked to fill out the Mankoski pain questionnaire for 3 consecutive cycles. This score acted as a control group mean for pain experienced without treatment. They were also asked to keep a medication diary (Appendix 2) indicating the type of medication taken, the amount taken and in which cycle.

At the same time the intervention group underwent treatment. They received their first treatment on around day 8-12 of their next menstrual cycle. They then rated their worst pain on the first day of menstruation using the Mankoski pain scale. This routine continued for 4 consecutive cycles. In total they received 3 treatments but they rated their

pain up until the 4th cycle. In total they participated for 5 months. This included the pre-treatment time.

Before each treatment, the participants in the intervention group were asked to empty their bladder due to the direct techniques on the associated viscera. The participants were then asked to undress to their underwear and then put on a medical robe if desired. The researcher then examined the participant for somatic dysfunction (appendix 9) and treated the participant accordingly. The techniques used included soft tissue, muscle energy techniques (MET) and high velocity low amplitude thrust (HVLA). The researcher then treated the associated visceral areas including the ovaries, uterus, bladder and large intestine using visceral (direct) techniques. Participants had one treatment session per cycle between days 8-12 of their menstrual cycle. The participants were then asked to rate their pain on the first day of menstruation for each menstrual cycle using the Mankoski pain scale. The participants were also asked to keep a medication diary to indicate the amount of medication they had taken, which medication was taken and which cycle. All treatments were performed in the student osteopathic clinic at Victoria University.

ANALYSIS OF DATA

Results for between and within group measures were analysed using SPANOVA with baseline scores as covariates. ANOVA was then used to compare the end score to the baseline scores. The computer program used was SPSS version 11. A significance level of $p = < .05$ was set. Information on medication use was also analysed with graphs using details such as strength of medication, cycle and amount used. Microsoft Excel was the computer program used to create the graphs.

RESULTS

In terms of the amount of pain experienced a SPANOVA analysis was performed using the baseline scores as covariates. Table 1 shows the mean and standard deviations for both groups.

Insert Table 1

A significant difference is seen in table two ($p = .000$) showing that treatment is having a significant effect on pain scores.

Insert Table 2

This is further verified in table 3 with an ANOVA analysis where within subjects effects compared the last cycle of the experimental group to the baseline score. Again the significance is at $p = .000$ with an alpha power of 1.000 (eta squared = .720). Tests of between subjects effects again showed that treatment had a large effect on pain scores ($p = .001$, alpha observed power = 1.000) when compared to the baseline data.

Insert Table 3

In terms of the medication taken, the experimental group had a decrease in the amount of medication taken. Figures 1-3 show the amount of medication taken, the type of medication and during which cycle it was taken. Each cycle can be compared to the baseline in the experimental group and the two groups can be compared to themselves for each of the different types of medication. Naproxen sodium was only taken by the

experimental group. The amount of medication taken was measured in milligrams (mg). Generally the control group took more medication compared to the experimental group. Figure 1 looks at the amount of naproxen sodium taken in the experimental group compared to the baseline. The results show that compared to the baseline there is a decrease in naproxen sodium taken, especially in the last cycle where none was taken.

Insert Figure 1

Figure 2 compares the amount of ibuprofen taken in the control group to the experimental group. The experimental group also has a baseline measurement. When compared to the experimental group, the control group took four times more ibuprofen to begin with, however the amount taken in the control group was quite stable the whole time. In the experimental group however, the amount of ibuprofen taken was less than the baseline and decreased over time with the last cycle taking the least amount.

Insert Figure 2

Figure 3 compares the amount of paracetamol taken. The results are similar to those of ibuprofen where there was an increased amount taken in the control group compared to the experimental group. When comparing the experimental group to the baseline score, there was a decreased amount taken over time, again in the last cycle.

Insert Figure 3

DISCUSSION

Previous studies into the area of primary dysmenorrhea have focused mainly on spinal manipulation as a form of treatment and although the treatment has been successful it has been seen as a short-term solution. [2] Chadwick and Morgan[17] conducted a study similar to this in that a variety of techniques were used. Their study concluded that an incorporation of other techniques such as visceral is an integral part of the holistic treatment of a patient with primary dysmenorrhea. It allows for the "potential to alter viscero-somatic hyper-excitability, associated with primary dysmenorrhea, by incorporation of manual visceral techniques". [17]

The study used a variety of techniques similar to that of Chadwick and Morgan [17]. Firstly the participant was assessed for somatic dysfunction and treated accordingly. The main areas that were focused on were the lower thoracics, upper lumbars, sacrum, pelvis, lumbar erector spinae, psoas, quadratus lamborum, diaphragm and pelvic floor musculature (Appendix 9). The techniques applied included soft tissue, muscle energy techniques (MET) and high velocity low amplitude techniques (HVLA). The same techniques or combinations of techniques were not performed on everyone. Visceral techniques were then used that directly influenced the bladder, uterus, ovaries, diaphragm and large intestine. Stretching, articulation and positional release techniques were performed on and around these organs aiming to decrease muscle hypertonia and provide increased movement of the organs. The techniques were similar to those used in Barral and Mercier.[14]

The effects of osteopathic treatment on menstrual pain levels

The first aim of the study was to see if osteopathic treatment provided a reduction in pain experienced by women with primary dysmenorrhea. This study demonstrated that there was a reduction of pain in the experimental group when compared to the control group and to the baseline scores. There was a high significance level ($p<.05$) as was the power indicating that osteopathic treatment of primary dysmenorrhea may be a successful tool in practice. Of the participants it is worth noting that three of the ten participants experienced no pain by the third treatment, four experienced a score of three or less on the Mankoski pain scale and three experienced between four and five. A significance level of $p = .000$, with an observed power of 1.000 was obtained when the baseline score of the experimental group was compared to the last score, indicating that with time there was a definite reduction in pain if treatment was administered. When comparing the control group to the experimental group there was also a reduction of pain over time ($P = .000$, power 1.000).

The effects of Osteopathic treatment on medication use

Another aim of the study was to measure whether there was a decrease in the use of medication in the experimental group when compared to the control group. During the study each participant only took one type of medication, if any. Figures 1-3 show the graphs with each type of medication. Noticeably the experimental group took three types of medications (paracetamol, ibuprofen and naproxen sodium) whereas the control group only took two (ibuprofen and paracetamol). This may explain why in figures 2

(ibuprofen) and 3 (paracetamol) the control group took more medication overall than did the experimental group. Nevertheless the general trend is that the control group took a stable amount of medication throughout the study, whereas the experimental group had a decrease in the amount of medication taken with time and compared to the baseline score. Figure 1 demonstrates the amount of naproxen sodium taken. Each cycle can be compared to the baseline score. It can be seen that with time, and especially in the last cycle there was a definite decrease in medication taken compared to the baseline. Figure 2 demonstrates the amount of ibuprofen taken and compares this to the control group as well as the baseline measures. Clearly the control group took more medication even when compared to the experimental group. This may be due to the fact that one single participant (an employee at a pharmacy) took an increased amount of ibuprofen (max amount but not over) compared to any one else. Even so there was a decrease in ibuprofen taken with time in the experimental group, again especially in the last cycle. Figure 3 compares the amount of paracetamol taken. It can be seen that the control group as a whole took an increased amount of paracetamol compared to the experimental group.

These results show a positive improvement on past research. Nielsen[13] only treated with visceral techniques, however interestingly, of her five participants there were 2 that markedly improved, whereas the other three had moderate improvement. The two that had higher improvement levels had had manipulation to their lower thoracic or lumbar areas whereas the other three had visceral treatment only. This study supports these results as a combination of techniques proved to have significant findings in the decrease of pain. Chadwick and Morgan[17] further verified this as their study incorporated a variety

of techniques with great success. The results from this study and from previous research high-light the fact that a combination of techniques, which is what would most likely be used in practice, may give a more successful result in treating PD than would exclusive techniques.

Limitations

A limitation of this study was the time factor. Baseline scores were obtained for only one cycle and although the participants in the experimental group stated that their pain levels did not alter much from cycle to cycle more measurements may have made the results more credible. Obtaining post treatment scores after the cessation of the treatment for further cycles may indicate whether there is a longer lasting effect of treatment. Another addition may include a placebo or sham group so as to further validate if the treatment was having an effect. However this study wanted to measure whether some treatment was better than no treatment.

ACKNOWLEDGEMENTS

We thank the participants for their involvement in the study. We would also like to thank Andrea Mankoski for allowing us to use her pain scale.

REFERENCES

[1] *Merck Manual of Diagnosis and Therapy (The),* 17th Ed., Merck Research Laboratories, U.S.A

[2] Kokjohn K, Schmid DM, Triano JJ, Brennan PC. The Effects of Spinal Manipulation on pain and prostaglandin levels in women with primary dysmenorrhea. *J Manipulative Physiol Ther*. 1992;15:279-85

[3] Wood C. Advances in the Treatment of Menstrual Disorders. *Current Therapeutics*. 2000: 42 - 415

[4] Polus. B, Henry S.J, Walsh. M.J. Dysmenorrhea – to Treat or Not to Treat? *Chiropr J Aust*. 1996;26(1): 21-4

[5] Mims, issue No. 5, 2001

[6] Trickey. R. *Women, Hormones and the Menstrual Cycle – Herbal and Medical Solutions from Adolescence to Menopause,* Allen and Unwin, Australia; 1998

[7] Hitchcock. M.E., The Manipulative approach to the management of dysmenorrhea*, J. AM. Osteo Assoc*. 1976; 73: 157-106

[8] Upfal.J., *The Australian drug guide,* Bookman press Pty Ltd, Australia; 2002

[9] Tickell.J. *What's that Pill doing to you? Dr. John Tickell's Drug Guide.* Information Australia, Australia; 2000

[10] Nichols J, Nicholls Dr. B, Kiatos Dr. J. Osteopathic examination findings in women with primary dysmenorrhea*. Victorian University Faculty of Human Development, Osteopathic Medicine, School of Health sciences.* 22nd October, 2001. (unpublished observations)

[11] Greenman.P.E. *Principles of Manual Medicine, second ed.* Lippincott Williams & Wilkins, Baltimore, USA: 1996.

[12] Vernon HT, Dhami, Howely TP, Annett R. Spinal manipulation and beta-endorphins: a controlled study on the effect of a spinal manipulation on plasma beta-endorphin levels in normal males. *J Manipulative Physiol Ther.* 1986;15:115-23

[13] Nielsen C, Nicholls Dr. B, Kiatos Dr. J, The effect of visceral (osteopathic) treatment on young women with primary dysmenorrhea- a pilot study, *Dep. Health sciences, Faculty of Human Development, Victoria University*, 2002 (unpublished observations)

[14] Barral. J. P & Mercier. P. *Visceral Manipulation*. Eastland Press, Seattle1. 1151414: 174-1140, 227-230, 245, 2415-50, 252

[15] Walsh MJ, Polus, BI. A randomized, placebo-controlled clinical trial on the efficacy of chiropractic therapy on premenstrual syndrome. *J Manipulative Physiol Ther*. 1999; 22: 582-5

[16] Proctor ML, Hing W, Johnson TC, Murphy PA. Spinal Manipulation for Primary and Secondary Dysmenorrhea. *Cochrane database Syst Rev.* 2001; 4: CD002119

[17] Chadwick K, Morgan A. The Efficacy of Osteopathic Treatment for Primary Dysmenorrhea in Young Women. *American Academy of Osteopathy*. 1996; 6(3): 15-17, 29&30

[18] Liebl NA, Butler LM. A Chiropractic approach to the treatment of Dysmenorrhea. *Journal of Manipulative Physiological Therapies*. 1990; 13:101-106

[19] Evans K. Self perceptions of pain as reported by patients with chronic pain receiving aquatic therapy versus land based therapy. *College Misericordia. 2002.* (unpublished thesis)

[20] Published by the office of Primary and Ambulatory Care and the Employee Education System Patient Education Program in association with the US Department of Veteran Affairs, *Patient Education in Primary care.* 3: (issue 4): 2

Fig 1. Naproxen Sodium taken in Experimental group including baseline

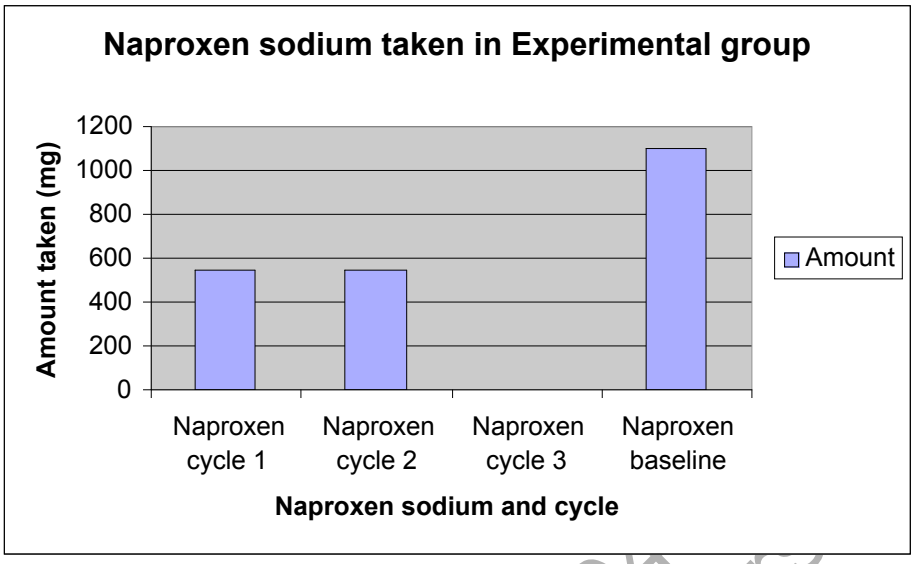

Fig 2. Ibuprofen: Experimental Vs Control

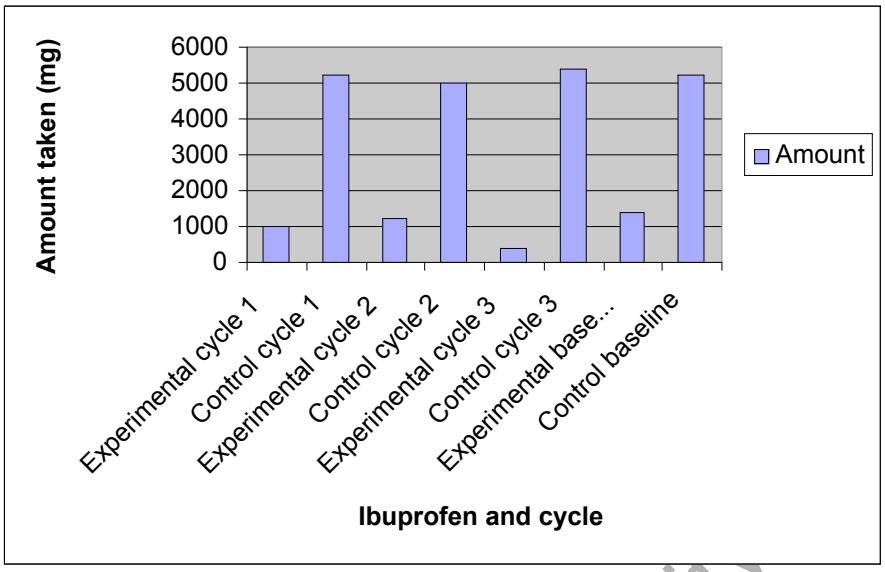

Fig 3. Paracetamol: Experimental Vs Control

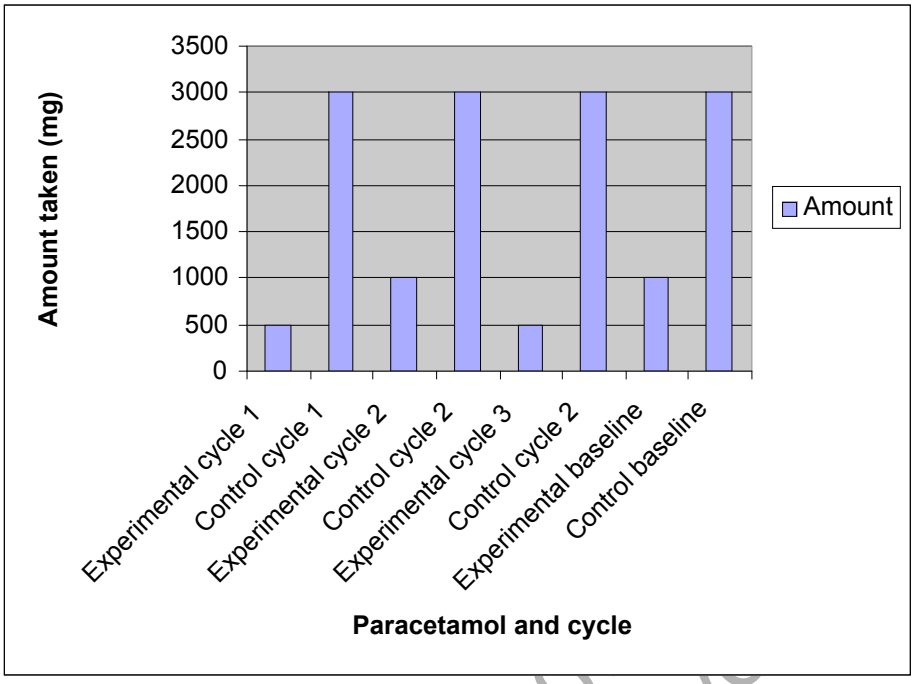

Table 1

Descriptive Statistics: Means and Standard deviations

	Participant	Mean	Std. Deviation	N
Score 1	Control	6.20	.919	10
	Experimental	4.60	1.897	10
	Total	5.40	1.667	20
Score 2	Control	5.80	.919	10
	Experimental	3.55	1.536	10
	Total	4.68	1.688	20
Score 3	Control	5.80	1.549	10
	Experimental	2.20	1.814	10
	Total	4.00	2.471	20

Table 2

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	4.718	1	4.718	1.504	.237	.081	1.504	.212
Baseline	27.886	1	27.886	8.890	.008	.343	8.890	.802
Participant	111.544	1	111.544	35.562	.000	.677	35.562	1.000
Error	53.322	17	3.137					

a Computed using alpha = .05

Table 3

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	Df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power (a)
Time	Sphericity Assumed	54.056	1	54.056	46.306	.000	.720	46.306	1.000
	Greenhouse-Geisser	54.056	1.000	54.056	46.306	.000	.720	46.306	1.000
	Huynh-Feldt	54.056	1.000	54.056	46.306	.000	.720	46.306	1.000
	Lower-bound	54.056	1.000	54.056	46.306	.000	.720	46.306	1.000
time * Participant	Sphericity Assumed	37.056	1	37.056	31.744	.000	.638	31.744	1.000
	Greenhouse-Geisser	37.056	1.000	37.056	31.744	.000	.638	31.744	1.000
	Huynh-Feldt	37.056	1.000	37.056	31.744	.000	.638	31.744	1.000
	Lower-bound	37.056	1.000	37.056	31.744	.000	.638	31.744	1.000
Error(time)	Sphericity Assumed	21.012	18	1.167					
	Greenhouse-Geisser	21.012	18.000	1.167					
	Huynh-Feldt	21.012	18.000	1.167					
	Lower-bound	21.012	18.000	1.167					

a Computed using alpha = .05

APPENDIX 1

Mankoski Pain Scale

Indicate Group and participant No.: ----------

Baseline score	1st score	2nd score	3rd score		
				0	Pain Free.
				1	Very minor annoyance - occasional minor twinges.
				2	Minor annoyance – occasional strong twinges.
				3	Annoying enough to be distracting.
				4	Can be ignored if you are really involved in your work, but still distracting.
				5	Can't be ignored for more than 30 minutes.
				6	Can't be ignored for any length of time, but you can still go to work and participate in social activities.
				7	Makes it difficult to concentrate, interferes with sleep. You can still function with effort.
				8	Physical activity severely limited. You can read and converse with effort. Nausea and dizziness set in as factors of pain.
				9	Unable to speak. Crying out or moaning uncontrollably – near delirium.
				10	Unconscious. Pain makes you pass out.

APPENDIX 2

MEDICATION DIARY

Indicate Group and Participant No. ----------

Date	Painkillers used	Dosage	Day in cycle

APPENDIX 3

INFORMATION TO PARTICIPANTS FORM

We invite you to participate in a 4-month study that will investigate the effect of osteopathic treatment on menstrual cycle pain (primary dysmenorrhea). There will be two treatment procedures used. Firstly any somatic (body –framework) dysfunction will be treated. Then, visceral osteopathic techniques will be used on the abdominal area.

You will be asked to sign a consent form. However you are free to withdraw from the study at any stage. A gynaecological, medical and menstrual history will be taken to determine whether the cause of your pain is from primary dysmenorrhea. It will also determine whether it is safe for you to commence treatment. After this the study will commence.

The study will have two groups. One group will be receiving osteopathic treatment, the other group will not. The groups will be chosen randomly by coin toss, and you will either be assigned to group A, which is the group not receiving treatment, or group B, which is the group receiving treatment. Before treatment begins and regardless of what group you are in, you will have to rate your pain on a scale given to you called the Mankoski pain questionnaire. This will be done at the time of your pain. This will give us a base at which to compare further results to.

If you are in the group not receiving osteopathic treatment you will be required to fill out a Mankoski pain questionnaire that rates your pain on a scale of 1-10. You will also be required to keep a medication diary. If you are taking medication for your pain you are encouraged to continue if need be. You will need to rate your pain and keep a diary for 3 consecutive months. The practitioners will tell you when to begin rating your pain. Both the Mankoski pain questionnaire and the table on which to keep a diary of your medication use will be given to you.

If you are in the group receiving osteopathic treatment you will be required to undress (in private) down to your underwear, a gown will be provided and blankets will be used for draping. The practitioner will then commence treatment. Firstly the practitioner will examine you for any somatic (body –framework) dysfunctions and treat you accordingly. The areas that will be looked at are the thoracic (middle back), lumbar (lower back), abdominal and pelvic regions. The treatment may involve the use of high velocity low amplitude manipulation. This is where your spine may be placed in a position and a quick thrust applied sometimes with a “pop” sound. Other treatments may involve stretching, soft tissue massage and muscle energy techniques (MET). MET is a gentle technique that uses your muscles to enhance movement, circulation and strength.

The second treatment is the use of visceral techniques. The treatment will be applied specifically to your uterus and surrounding organs. This will involve the practitioner putting his/her hands on your lower abdomen and pelvis and applying gentle stretching techniques.

This treatment will be carried out between days 8-12 of your menstrual cycle for 3 cycles. After the treatment and during your next period you will be required to fill out a pain scale that rated your pain for that cycle as well as keep a medication diary. In all you will be receiving 3 treatments. You will also be asked not to receive any other treatment for period pain while you are in the study.

There are some potential risks that are associated with the study. There is a possibility that you will experience discomfort during or after the treatment. There are potential risks associated with manipulation. The most serious is spinal cord compression or fracture of the vertebrae with the chance of this happening being about 1 in 400,000-2million manipulations. Other minor complications may include local pain or discomfort. The practitioner will be as gentle as possible. A full medical history will be taken to rule out any contraindications to any of the treatment. Only senior students and qualified practitioners will be performing treatments.

The questionnaires will be kept completely confidential. You will not need to supply your name, as you will have identification numbers. Completion of the questionnaire will be taken to imply consent. You are free to ask questions regarding any aspect of the study at any time. You are free to withdraw from the study at anytime.

If you are in the group receiving treatments, the first treatment will take between 1- 1 _ hrs to allow time for the completion of full case histories; subsequent treatments should only take _ - 45mins. If you are in the group not receiving treatment, you will be offered treatment at the conclusion of the study if the treatment proves to be beneficial.

Any queries about your participation in this project may be directed to the principal investigator (Name: Dr. Brian Nicholls ph. (03) 9248 1150). If you have any other queries or complaints about the way you have been treated, you may contact the secretary, University Human Research Ethics Committee, Victoria University, PO Box 14428 MC, Melbourne, 8001 (ph. (03) 9688 4710)

APPENDIX 4

Consent Form for Participants Involved in Research

CERTIFICATION BY PARTICIPANT

I**,**
of

certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the study entitled:

Osteopathic Treatment in Participants with Primary Dysmenorrhea.

being conducted at Victoria University by:

Dr Brian Nicholls DO, MA, Osteopath, Dr Jim Kiatos MB. BS. and Rosette Pirritano, student in the Master of Health Science (Osteopathy) program.

I certify that the objectives of the study, together with any risks to me associated with the procedures listed hereunder to be carried out in the study, have been fully explained to me by Dr Brian Nicholls or Rosette Pirritano, and that I freely consent to participation involving the use on me of the following procedures.

Objectives:
The study aims to investigate the effectiveness of Osteopathic treatment in participants with primary dysmenorrhea. Specifically it aims to investigate whether osteopathic treatment can decrease the pain associated with primary dysmenorrhea and as well as the amount of analgesic medication used.

Procedures:
Participants not involved in the treatment group will be required to fill out a Mankoski pain questionnaire that rates your pain on a scale of 1-10. You will also be required to keep a medication diary. If you are taking medication for your pain you are encouraged to continue if need be. You will need to rate your pain and keep a diary for 3 consecutive months. The practitioners will tell you when to begin rating your pain. Both the Mankoski pain questionnaire and the table on which to keep a diary of your medication use will be given to you.

Participants will be required, if in the treatment group, to disrobe, wearing a bra and underpants and the option of wearing a medical robe if desired. Participants will then be assessed for any somatic dysfunction related to their middle and lower back as well as their pelvis. Appropriate osteopathic treatment will be given.

Participants will then be asked to lie on their back with their knees bent slightly. Their lower body will be draped with towels and if a gown is worn, it will be raised above the belly button so that the abdomen can be exposed. The practitioner will then place their hand on the participant's abdomen and using light and deep pressure, will palpate the underlying organs including the uterus. Depending on the findings the practitioner will then apply gentle stretching techniques that will encourage movement of the uterus and surrounding organs. At the completion of the treatment participants will be asked to dress. Participants will be required to fill in a pain scale following their next period.

Risks:
The use of gentle visceral or other techniques such as stretching, soft tissue and muscle energy techniques may cause some discomfort during or after the treatment but do not pose any significant physical risk.

The use of high velocity low amplitude thrust (HVLA) may also cause some discomfort during or after the procedure. Osteopathic Manipulation is a direct technique applied to joint restrictions. The joint is taken to its restrictive barrier, from there a very quick, small, controlled thrust is applied; this moves the joint past the restrictive barrier. The joint is now free to move further than the previous restriction. When performing osteopathic manipulation there is the slight possibility of complications.

According to Gibbons and Tehan (2000), the most serious non-reversible complications of HVLA of the thoracic and lumbar spine are spinal cord compression and cauda equina syndrome. Cauda equina syndrome is the compression of the lowest part of the spinal cord causing symptoms such as loss of sensation in the saddle region, difficulties with urination or defecation, motor weakness and gait disturbances. Substantive reversible impairment during HVLA may include disc herniation, disc prolapse, nerve root compression or fracture. Transient complications may include local pain or discomfort, radiating pain, or paraesthesia. Serious complications are very rare with 1 journal stating that serious complications can range from 1 in 2 million manipulations or 1 in 400,000 manipulations with most of these associated with cervical spine manipulation. (Stevinson, Ernst, 2002). Another journal looked at 6 studies that examined 2,000 participants. There

was not a single case of a serious adverse event reported. However about 50% of participants experienced mild transient effects such as local discomfort.

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed: **.....** }

Witness other than the experimenter: } **Date: .....**

.....}

Any queries about your participation in this project may be directed to the researcher (Name: Dr Brian Nicholls ph. 92481150). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

APPENDIX 5

MENSTRUAL AND GYNAECOLOGICAL HISTORY

Participant No:

- **Have you ever been pregnant or had children?**

- **How soon after you first started getting your periods did your pain start?**

- **How soon do you get pain when you get your period? Immediately? First day? Second day?**

- **Using the Mankoski pain questionnaire what would you rate your pain to be on average?**

- **How regular are your cycles? Are they within +/- 3 days.**

- **Have you had or do you have a history of endometriosis?**

- **Are you or have you been on the birth control pill? If you were and are not anymore when did you stop?**

- **Has your period changed lately in terms of regularity or flow?**

- **Do you suffer from or have you been diagnosed of any other gynaecological conditions?**

APPENDIX 7

Raw Data

Participant	Baseline	Score 1	Score 2	Score 3	Weight	Height	Age
1	5	5	4	3	59	162	21
1	6	6	5	6	55	152	22
1	6	5	6	5	58	159	23
1	7	7	6	7	59	156	23
1	6	6	6	6	60	160	22
1	6	5	5	5	63	155	30
1	6	7	6	4	60	159	24
1	7	7	7	7	61	160	19
1	7	7	7	8	60	156	24
1	6	7	6	7	65	167	23
2	7	4	3	0	60	155	24
2	6.5	4	4.5	2	53	153	24
2	7	6	5	4	54	150	18
2	6	6	4	2	70	170	23
2	7	5	4	0	56	168	20
2	6	7	2	2	53	158	24
2	6	1	1	0	60	165	30
2	6	2	2	4	67	172	21
2	6	5	4	3	57	156	24
2	7	6	6	5	58	163	24

1= Control group

2= Experimental group

APPENDIX 8

SPSS Statistical Output Data

Within-Subjects Factors

Measure: MEASURE_1

time	Dependent Variable
1	Score1
2	Score2
3	Score3

Descriptive Statistics

	Participant	Mean	Std. Deviation	N
Score 1	Control	6.20	.919	10
	Experimental	4.60	1.897	10
	Total	5.40	1.667	20
Score 2	Control	5.80	.919	10
	Experimental	3.55	1.536	10
	Total	4.68	1.688	20
Score 3	Control	5.80	1.549	10
	Experimental	2.20	1.814	10
	Total	4.00	2.471	20

Multivariate Tests(c)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Time	Pillai's Trace	.074	.640(b)	2.000	16.000	.540	.074	1.279	.138
	Wilks' Lambda	.926	.640(b)	2.000	16.000	.540	.074	1.279	.138
	Hotelling's Trace	.080	.640(b)	2.000	16.000	.540	.074	1.279	.138
	Roy's Largest Root	.080	.640(b)	2.000	16.000	.540	.074	1.279	.138
time * Baseline	Pillai's Trace	.053	.447(b)	2.000	16.000	.647	.053	.895	.110
	Wilks' Lambda	.947	.447(b)	2.000	16.000	.647	.053	.895	.110
	Hotelling's Trace	.056	.447(b)	2.000	16.000	.647	.053	.895	.110

	Roy's Largest Root	.056	.447(b)	2.000	16.000	.647	.053	.895	.110
time * Participant	Pillai's Trace	.273	3.006(b)	2.000	16.000	.078	.273	6.011	.502
	Wilks' Lambda	.727	3.006(b)	2.000	16.000	.078	.273	6.011	.502
	Hotelling's Trace	.376	3.006(b)	2.000	16.000	.078	.273	6.011	.502
	Roy's Largest Root	.376	3.006(b)	2.000	16.000	.078	.273	6.011	.502

a Computed using alpha = .05
b Exact statistic
c Design: Intercept+Baseline+Participant Within Subjects Design: time

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Time	Sphericity Assumed	1.165	2	.582	.519	.600	.030	1.038	.128
	Greenhouse-Geisser	1.165	1.665	.700	.519	.568	.030	.864	.121
	Huynh-Feldt	1.165	2.000	.582	.519	.600	.030	1.038	.128
	Lower-bound	1.165	1.000	1.165	.519	.481	.030	.519	.105
time * Baseline	Sphericity Assumed	.666	2	.333	.297	.745	.017	.594	.093
	Greenhouse-Geisser	.666	1.665	.400	.297	.706	.017	.494	.090
	Huynh-Feldt	.666	2.000	.333	.297	.745	.017	.594	.093
	Lower-bound	.666	1.000	.666	.297	.593	.017	.297	.081
time * Participant	Sphericity Assumed	10.376	2	5.188	4.624	.017	.214	9.247	.743
	Greenhouse-Geisser	10.376	1.665	6.232	4.624	.024	.214	7.699	.683
	Huynh-Feldt	10.376	2.000	5.188	4.624	.017	.214	9.247	.743
	Lower-bound	10.376	1.000	10.376	4.624	.046	.214	4.624	.527
Error(time)	Sphericity Assumed	38.151	34	1.122					
	Greenhouse-Geisser	38.151	28.306	1.348					
	Huynh-Feldt	38.151	34.000	1.122					
	Lower-bound	38.151	17.000	2.244					

a Computed using alpha = .05

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Time	Linear	.711	1	.711	.445	.514	.026	.445	.097
	Quadratic	.454	1	.454	.703	.413	.040	.703	.124
time * Baseline	Linear	.220	1	.220	.137	.715	.008	.137	.064
	Quadratic	.446	1	.446	.692	.417	.039	.692	.123
time * Participant	Linear	10.154	1	10.154	6.351	.022	.272	6.351	.661
	Quadratic	.223	1	.223	.345	.565	.020	.345	.086
Error(time)	Linear	27.180	17	1.599					

Quadratic	10.970	17	.645					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	4.718	1	4.718	1.504	.237	.081	1.504	.212
Baseline	27.886	1	27.886	8.890	.008	.343	8.890	.802
Participant	111.544	1	111.544	35.562	.000	.677	35.562	1.000
Error	53.322	17	3.137					

a Computed using alpha = .05

1. Participant

Measure: MEASURE_1

Participant	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	6.091(a)	.328	5.400	6.783
Experimental	3.292(a)	.328	2.601	3.983

a Covariates appearing in the model are evaluated at the following values: Baseline = 6.33.

Multivariate Tests(c)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Time	Pillai's Trace	.720	46.306(b)	1.000	18.000	.000	.720	46.306	1.000
	Wilks' Lambda	.280	46.306(b)	1.000	18.000	.000	.720	46.306	1.000
	Hotelling's Trace	2.573	46.306(b)	1.000	18.000	.000	.720	46.306	1.000
	Roy's Largest Root	2.573	46.306(b)	1.000	18.000	.000	.720	46.306	1.000
time * Participant	Pillai's Trace	.638	31.744(b)	1.000	18.000	.000	.638	31.744	1.000
	Wilks' Lambda	.362	31.744(b)	1.000	18.000	.000	.638	31.744	1.000
	Hotelling's Trace	1.764	31.744(b)	1.000	18.000	.000	.638	31.744	1.000
	Roy's Largest Root	1.764	31.744(b)	1.000	18.000	.000	.638	31.744	1.000

a Computed using alpha = .05
b Exact statistic
c Design: Intercept+Participant Within Subjects Design: time

Mauchly's Test of Sphericity(b)

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon(a) Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Time	1.000	.000	0	.	1.000	1.000	1.000

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+Participant Within Subjects Design: time

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Time	Sphericity Assumed	54.056	1	54.056	46.306	.000	.720	46.306	1.000
	Greenhouse-Geisser	54.056	1.000	54.056	46.306	.000	.720	46.306	1.000
	Huynh-Feldt	54.056	1.000	54.056	46.306	.000	.720	46.306	1.000
	Lower-bound	54.056	1.000	54.056	46.306	.000	.720	46.306	1.000
time * Participant	Sphericity Assumed	37.056	1	37.056	31.744	.000	.638	31.744	1.000
	Greenhouse-Geisser	37.056	1.000	37.056	31.744	.000	.638	31.744	1.000
	Huynh-Feldt	37.056	1.000	37.056	31.744	.000	.638	31.744	1.000
	Lower-bound	37.056	1.000	37.056	31.744	.000	.638	31.744	1.000
Error(time)	Sphericity Assumed	21.012	18	1.167					
	Greenhouse-Geisser	21.012	18.000	1.167					
	Huynh-Feldt	21.012	18.000	1.167					
	Lower-bound	21.012	18.000	1.167					

a Computed using alpha = .05

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Time	Linear	54.056	1	54.056	46.306	.000	.720	46.306	1.000
time * Participant	Linear	37.056	1	37.056	31.744	.000	.638	31.744	1.000
Error(time)	Linear	21.013	18	1.167					

a Computed using alpha = .05

APPENDIX 9

Area of Body to be assessed	Participant group and No. Tick if somatic dysfunction present		
T10			
T11			
T12			
Thoracolumbar			
L1			
L2			
L3			
L4			
L5			
Lumbosacral			
Sacrum			
Thoracic Erector Spinae			
Quadratus Lumborum			
Lumbar Erector Spinae			
Gluteus Maximus			
Gluteus Medius			
Piriformis			
Diaphragm			
Psoas			
Inguinal ligament region			
Hypochondrial region			
Epigastric region			
Iliac region			
Suprapubic region			

APPENDIX 10

Medication Usage in Experimental and Control groups

Experimental group	Amount
Naproxyn cycle 1	550
Naproxen cycle 2	550
Naproxen cycle 3	0
Naproxen baseline	1100

Paracetamol	Amount
Cycle 1 Experimental	500
Cycle 1Control	3000
Cycle 2 Experimental	1000
Cycle 2 Control	3000
Cycle 3 Experimental	500
Cycle 3 Control	3000
Baseline Experimental	1000

Ibuprofen	Amount
Cycle 1 experimental	1000
Cycle 1 control	5200
Cycle 2 experimental	1200
Cycle 2 control	5000
Cycle 3 experimental	400
Cycle 3 control	5400
Baseline experimental	1400

Page: 12

[BRV1] I think it may be worth mentioning that 22 participants were recruited and then 2 were excluded due to their medical history leaving the 20 that completed the study