MASTERS OF HEALTH SCIENCE

JOURNAL ARTICLE PROPOSAL

Effects of osteopathic treatment on people with psoriatic arthritis. A pilot study.

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ABSTRACT

Background & Objectives: People with psoriatic arthritis seek complementary medical treatment, such as osteopathy, as a sole form of treatment, or as a complement to conventional treatment. The aim of this case series design was to determine the effects of osteopathic treatment on the symptoms, and health related quality of life (**HRQOL**) in people with psoriatic arthritis.

Methods: 4 participants, with psoriatic arthritis, underwent 5 osteopathic treatments at one-week intervals. The Bath-Ankylosing-Spondylitis-Disease-Activity-Index (BASDAI) and Medical Outcomes Study Short-Form Health Survey (SF-36) were used to measure treatment outcome at one-week intervals, and at one-week follow-up (week 6).

Results: Treatment resulted in some mean improvements in symptoms and HRQOL domains, in the participants.

Conclusion: The results demonstrate that osteopathic treatments are capable of producing symptomatic relief and improvements in HRQOL. The limited number of participants in the study limits generalization of the findings, but gives impetus to further research in this area.

Keywords: Psoriatic arthritis, osteopathy, osteopathic medicine, manual therapy, spondyloarthropathy, health related quality of life (SF-36).

INTRODUCTION

Psoriasis is a common skin condition that affects about 1-3 % of the general population.[1, 2] Approximately 10 - 30 % of people with psoriasis may develop psoriatic arthritis (PsA), a spondyloarthropathy, that predominantly affects the peripheral joints of the hands and feet, sacroiliac joints and the spine.[3-6]

PsA can develop at any time. The peak age of onset is between 20-50 years, and affects both sexes equally.[3, 5] The majority have relatively mild symptoms with slow progression of the disease process. If left untreated, PsA may become more severe, unrelenting, and progressively disabling.

Clinical Features

The most common features include: pain, stiffness, swelling and tenderness of the joints and surrounding soft tissue; morning stiffness and tiredness; reduced range of motion; nail changes (e.g. pitting); back pain and stiffness.[3, 7]

The most widely used classification scheme for PsA is that of Moll and Wright, even though several sources [8-10] consider it to be inadequate. It lists the five main clinical patterns seen in PsA: 1) classic PsA of distal interphalangeal joints of hands and feet, 2) arthritis mutilans, 3) symmetric polyarthritis similar to rheumatoid arthritis (RA), 4) asymmetric oligoarthritis with dactylitis, and 5) sacroiliitis or spondylitis with or without peripheral joint involvement.[7] Although these groupings serve as guidelines, they do not allow for overlap between each group, leading to differences in the reported occurrence of each of these groups. The pattern, the extent of joint involvement, and the clinical course in PsA changes over time and in response to therapy, [11] with unpredictable exacerbations and remissions. The patient usually has a history (or strong family history) of psoriasis, with 75% of patients having psoriatic skin lesions before the onset of joint disease.[5] The severity and duration of the skin lesion has no affect on the onset and severity of arthritis.

Diagnosis often relies on the clinical history, presentation, physical examination, radiographic features and blood tests.[1] Laboratory investigations are

relatively non-specific and are used to rule out other diseases that may be affecting the joints.[7]

Because of the complexity of the diagnosis of PsA, any study using participants with this disease would require a formal medical diagnosis for all participants.

LITERATURE REVIEW

Allopathic Treatment

The general aims of treatment are suppression of disease activity, prevention of joint deformity and disability, preservation of musculoskeletal function, control of psoriasis, and education and emotional support.[12] These aims can be achieved by adopting a multidisciplinary approach, with treatments ranging from conventional methods (e.g., rheumatologist, dermatologists, surgeons) to rehabilitative and complimentary therapies (e.g., physiotherapy and osteopathy). [13, 14]

The choice of treatment for PsA is dependent on the presenting clinical features and the extent of the disease process. The most common care for PsA utilises a variety of medications under the care of a rheumatologist.[12] Medications used include, non-steroidal anti-inflammatory drugs (NSAIDs), disease-modifying antirheumatic drugs (DMARDs) and biologics.[1] " Several generations of each drug are now available." [15] However, there is still no single modality that has proven to be successful.[16] In a 1998 telephone interview of 6194 people with psoriasis, 40% of those interviewed said they felt frustrated with the ineffectiveness of their current therapies, and 32% reported that their treatment was not aggressive enough. [17] Given the less than satisfactory conventional treatment outcomes for people with psoriasis and PsA, it is not surprising that many people with PsA seek help in non-traditional medical modalities.

Osteopathy and other complementary and/or manual therapies

PsA can also be managed using therapies such as osteopathy, chiropractic, naturopathy, and Traditional Chinese Medicine, to name a few. Patients may choose to use these disciplines as the sole source of treatment, or as a complement to conventional treatment.[1] There are few published articles in the literature that show how complementary and manual therapies such as osteopathy, are effective in PsA. Nevertheless, many arthritis patients are seeking or are willing to try these disciplines to gain relief, especially patients with musculoskeletal symptoms.[18] In a study of RA and osteoarthritis (OA) patients, it was found that over half the patients had used some form of unconventional (complimentary) treatment to relieve pain.[19] Resources such as '**A Guide To Alternative Therapies**', [13] '**Update**' [20] and '**Arthritis Action**' [21] that discuss different treatment options, as well as by anecdotal reports from patients and health care practitioners regarding the beneficial outcomes of such treatment modalities in arthritis patients, show the growing popularity of these treatment modalities in the management of arthritis.

Only one published study was found that investigated manual therapy and PsA. This case study,[8] looked at the chiropractic management of a patient with combined OA and PsA. Marked improvements were seen in pain levels and activities of daily living, after twelve weeks of treatment. [8] Physiotherapy has also been reported as having a beneficial effect by improving joint mobility, preserving joint function, reducing joint inflammation, improving functional capabilities, and maximising the potential for normal emotional activities.[12, 22] Exercise, stretching, massage therapy, selective mobilisation techniques, rest, ice, heat, correct posture, balneotherapy and UV rays [22, 23] have also been reported, both in the literature and anecdotally, to be effective in psoriatic arthritic patients.

To date there have been no studies published addressing the effect of osteopathic treatment on PsA. In practice, many osteopaths treat patients with PsA as well as other forms of arthritis, such as OA, RA and ankylosing spondylitis (AS), who are said to benefit from treatment, both mentally and physically. Improved health related quality of life (HRQOL) [16] as well as relief from pain and distress [24] has been reported to occur in people with psoriatic arthritis when offered osteopathic treatment.

However, the beneficial outcomes of osteopathic treatment in patients with PsA will continue to remain anecdotal, until they are investigated by a clinical trial.

The development of 'arthritis has a significant impact on HRQOL in people with psoriasis.'[18] Reports have shown that people with PsA experience lower HRQOL compared with that of the general population [25, 26] HRQOL includes social, physical and psychological well-being, and encompasses the impact of disease and its relevant treatment on an individual's perception of their ability to lead a full and productive life.[27] HRQOL measures e.g., the Short-Form 36 (SF-36) [28] assess such things as pain, physical functioning, work/role limitations due to physical problems, role limitations due to emotional problems, mental health, social functioning, energy/fatigue, and general health perceptions. [29,30] HRQOL measures, such as the SF-36, are increasingly being used in the clinical setting to evaluate the effectiveness of therapeutic interventions, [25] and/or the effect that a disease has on an individual. Since a reduced HRQOL has been reported to be experienced by people with PsA, [18, 25, 26] a HRQOL measure, e.g., SF-36 was used in the present study, to assess whether osteopathic treatment had any effect on HRQOL in these individuals.

Self-reported symptoms (e.g., pain) are also important measures to evaluate the effectiveness of treatment in arthritis patients. The Bath ankylosing spondylitis disease activity index (BASDAI) [31] incorporates the five major symptoms of the spondyloarthropathies (e.g., fatigue, spinal pain, joint pain/swelling, areas of localized tenderness and morning stiffness) [31] to measure the disease status of an individual. If utilised before and after a treatment intervention, e.g. osteopathy, as in the present study, the BASDAI can be used to assess the effectiveness of a treatment intervention, by measuring the severity of the participants' symptoms and how they are affected by treatment.

Since there is no single treatment modality(s) that has been shown to be uniformly effective in the treatment of PsA, together with the relative lack of research into complementary/manual therapy interventions and PsA, there is an increasing need for more clinically based research, utilising common, validated outcome measures, into the possible benefits and effectiveness received by arthritis patients due to other treatment modalities, such as osteopathy.

The aim of this study was to determine the effects of osteopathic treatment on the symptoms, and HRQOL in people with PsA by using the BASDAI and the SF-36 health survey. Since the present study is a pilot study, the general trends in the participants' symptoms and HRQOL will be looked at, to help form the basis for future research.

MATERIALS AND METHODS

Study design

This study is a pilot study because, to date, the effect of osteopathic treatment on people with PsA has not been investigated in a published research investigation. A single-subject experimental design of a small group of participants (n=4) was utilised. Each participant was individually assessed and treated by an osteopath according to the examination findings. This study design with its client centred focus is ideally suited for researching human behaviour in the rehabilitation environment. Most rehabilitation practice settings have too few clients with similar characteristics to enable evaluation of treatment outcomes using randomised clinical trials.[32] The procedure for single subject research involves systematic, repeated measurement of treatment outcome.[33] The outcomes of osteopathic treatment on the participants was assessed using the BASDAI (Appendix A) and the SF-36 (Appendix B). The Victoria University Faculty of Human Research Ethics Committee granted ethical approval for the study.

Subjects

Four participants (2 males and 2 females), diagnosed with PsA by a rheumatologist, aged 22-55 years old, were involved. The participants had either polyarthritis or polyarthritis in association with spondylarthritis. Participants were recruited by a poster advertisement at Victoria University, 301 Flinders Lane, and via an email out on the Victoria University email system. All participants provided written informed consent (Appendix C) for inclusion and were instructed to maintain their current medication regime, and to continue with their normal daily activities.

Measurement of treatment outcome

The effects of osteopathic treatment were assessed using the self-reported BASDAI, and the SF-36 (Appendix A and B).

BASDAI

The BASDAI (Appendix A) is a self-administered instrument that consists of six 10cm horizontal visual analogue scales that measure severity of fatigue, spinal and peripheral joint pain, localised tenderness and morning stiffness (both qualitative and

quantitative), over a period of one week. It is quick (< 1 min) and simple to complete, has good test-retest-reliability (r = 0.93; p<0.001) [31], and good construct and internal validity [31] It is sensitive to change and scores in the testing of the instrument are well distributed over the range of the scale. [31] The BASDAI has shown good metric properties in patients with all forms of spondyloarthropathies, including PsA.[34]

SF-36 Health Survey Questionnaire

The SF-36 (Appendix B) is a self-reported questionnaire consisting of 36 domains with 9 subscales (8 interval and 1 ordinal), designed to measure functional status, well-being, and general perceptions of health. Scores in each domain can range from 0 to 100, and higher scores indicate better functioning and well-being. It is highly reliable (Cronbach alpha coefficient > 0.90) [25] and valid (r = 0.33-0.67) [25] for the measurement of health status in PsA, and takes 5 minutes to complete. [25, 28] It has high test-retest reliability (0.76). [30] Several arthritis studies have utilised the SF-36 as a measure to assess the effect of treatment intervention [26] and/or the effect of arthritis, on an individuals HRQOL [25, 29]

The surveys were administered to, and collected from the participants by the student investigator. The treating practitioner was blinded to the participants' scores on all instruments.

Procedure

The participants were fully informed about the requirements of the study, by an information to participants form (Appendix D), before providing their written consent for participation. The participants were informed that participation was completely voluntary, confidential, and that they were free to withdraw from the study at any time.

The participants received one osteopathic treatment a week for five weeks. The total duration of the study was six weeks. Each treatment session was seven days apart. This period was selected on the basis of clinical experiences of several osteopaths, as well as from a chiropractic case study.[8] Treatments were undertaken at the Victoria University Osteopathic Medicine Clinic, Melbourne. The participants

were treated under the direction of an experienced, qualified osteopath. The first treatment was one hour long, to allow for an adequate history and examination to be taken. Subsequent treatments were for half an hour.

The BASDAI and SF-36 were administered by the student investigator over a 6 week period. The BASDAI was administered once a week for 6 weeks before the commencement of each of the treatment sessions at weeks 1 through to 5 for the participants to complete. The SF-36 questionnaire was completed at week 1, before treatment was commenced, and at week 6 (at home). Since the participants were not required to be treated at week six, the week 6 BASDAI and SF-36 were given to the participants at the week 5 (final) treatment session in an envelope, and were returned to the investigators once completed.

Osteopathic Treatment Intervention

Each participant was individually assessed at the time of the study, and treated according to their structural and functional findings at the time of the consultation. The T.A.R.T model of diagnosis was used to identify a "somatic dysfunction", an osteopathic term that is defined as impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements.[35] Somatic dysfunction is identified by the T.A.R.T. model through palpation and stands for Tissue texture abnormalities (T), Asymmetry (A) in motion, static, tonicity, colour and temperature, Restriction (R) or altered range of motion of single joint, several joints or a region, and Tissue tenderness (T) in the areas of abnormality i.e., reproduction of the familiar pain and symptoms.[35, 36] The commonly used treatment approaches such as soft tissue massage, stretching, high velocity low amplitude thrust technique (HVLA), Muscle Energy Technique (MET), articulation, postural re-education and exercise advice [24] were used. The choice of technique chosen by the practitioner was dependant on the relevant examination findings and the techniques are routinely used in Osteopathic practice.[36, 37]

Statistical Analysis

The BASDAI was scored with the aid of a standard metric ruler. The SF-36 questionnaire was scored using the SF-36 Health Survey Manual and Interpretation

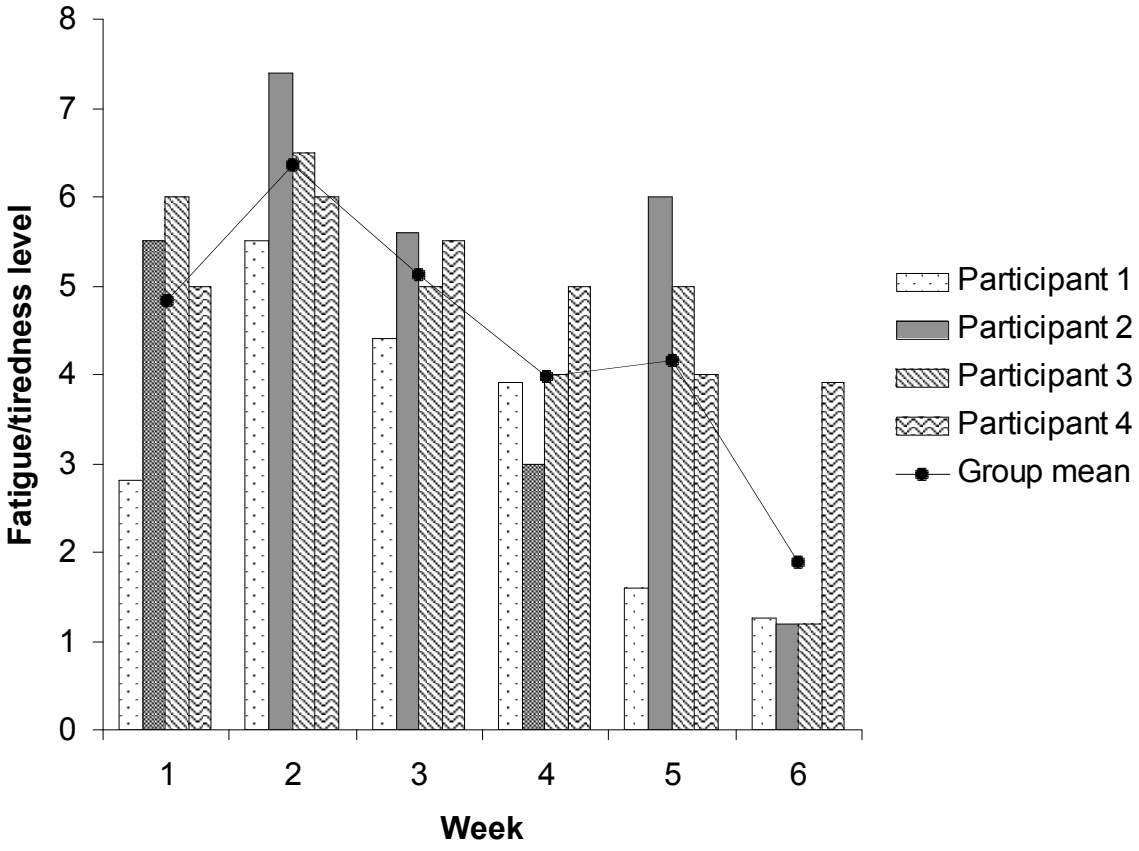
Guide.[28] All data received from the BASDAI, and SF-36 assessments were visually analysed and presented in graphical form. Cowell et al [38], report that visual analysis and graphical presentation of a group of single case studies is the easiest way of evaluating treatment outcomes and for the comparison of changes in each clinical feature. A one-way ANOVA was used to calculate the differences in the mean change in each of the participants' symptoms, over the six-week period, for each of the six symptoms recorded by the BASDAI. A Tukey post-hoc analyses was also performed. Effect sizes with ANOVA (Cohen's *f*, an omnibus measure of change) [39] were calculated for each of the six symptoms recorded on the BASDAI. Pre-treatment and post-treatment measurements were analysed for each of the subscales of the SF-36 using paired, two-tailed t-tests, and the pre-post effect sizes (Cohen's d, a standardised measure of change) [39] calculated. Effect size conventions were used to interpret the effect size. [39] Statistical significance was set at the alpha 0.05 level. All data was collated and analysed using SPSS for Windows, version 12.0.

RESULTS

BASDAI

Fatigue and tiredness

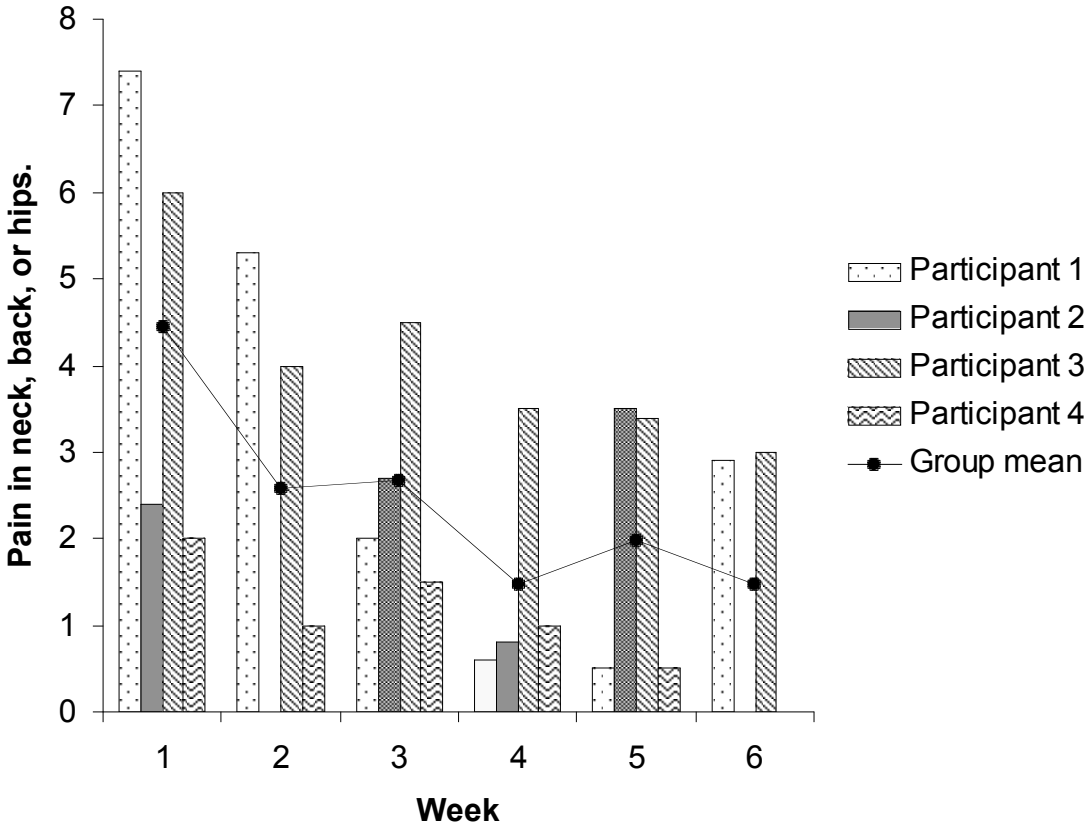
There was a mean reduction in the level of fatigue/tiredness experienced by the participants at the end of the study period, week 6, compared to that experienced at week 1 (Graph 1). At weeks 2 and 5 there was a mean increase in the level of fatigue/tiredness experienced. All participants experienced the least amount of fatigue/tiredness at week 6. The ANOVA for fatigue/tiredness found there to be a statistically significant difference between each of the treatment sessions ($F=5.917$, $p=0.002$), with a large effect size ($f=1.2$). Post-hoc testing (Tukey HSD) showed the difference to be between weeks 1 and 6 ($p=0.032$), 2 and 6 ($p=0.001$), and 3 and 6 ($p=0.016$).



Graph 1. Overall level of fatigue/tiredness experienced.

Overall Level of neck, back or hip pain experienced

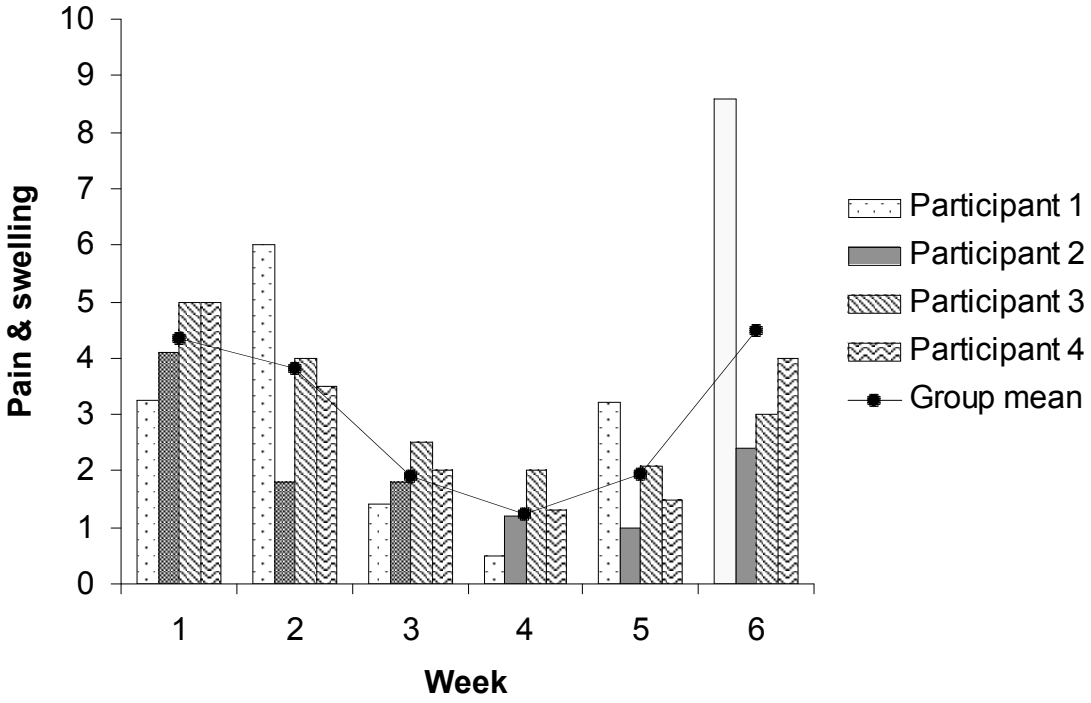
There was an overall mean reduction in the level of neck, back or hip pain experienced by the participants over the study period (Graph 2). The greatest mean reduction in the level of pain experienced was at week 4 and 6. Of note was that two participants had a complete resolution of their pain. Participant 2 experienced no pain at weeks 2 and 6, and participant 4, at week 6. No significant difference was seen in the participants' symptoms after each of the treatment sessions ($F=1.311$, $p=0.303$), even though a large effect size ($f=0.6$) was produced.



Graph 2. Overall level of neck, back or hip pain experienced.

Overall level of pain/swelling in joints other than neck, back or hips

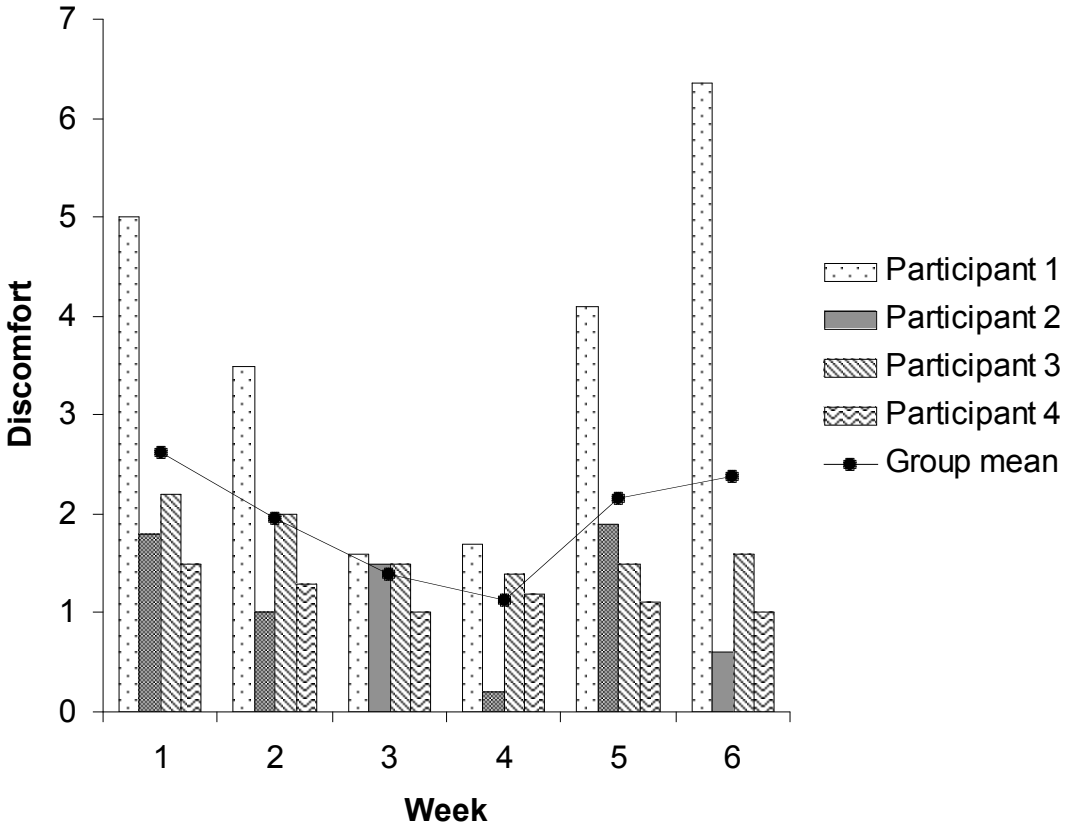
A gradual mean reduction in the participants' level of pain/swelling in joints other than the neck, back or hips occurred, reaching a minimum level at week 4, followed by a mean increase in the level experienced at weeks 5 and 6 (Graph 3).A significant difference in the participants' level of pain/swelling in joints other than the neck, back or hips was found between each of the treatment sessions ($F=3.681$, $p=0.18$), with a large effect size ($f=0.96$). Post-hoc analyses showed the difference to be between weeks 4 and 6 ($p=0.57$).



Graph 3. Overall level of pain/swelling experienced in joints other than the neck, back or hips.

Overall level of discomfort experienced

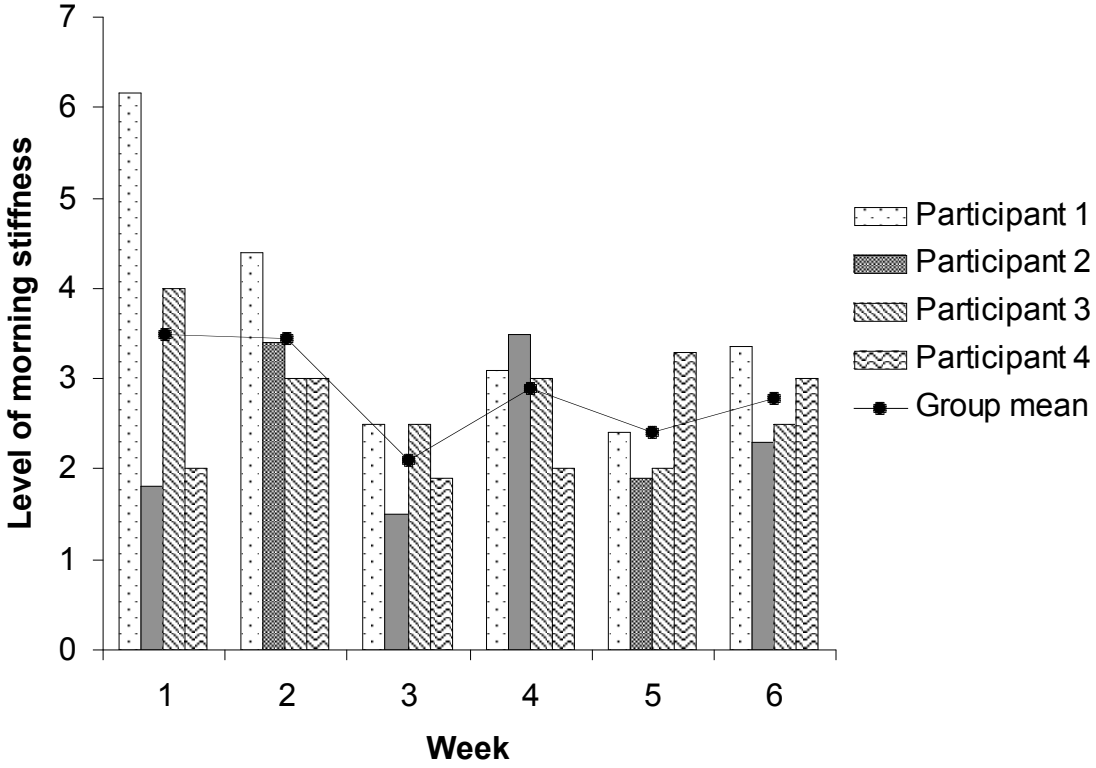
There was a gradual mean reduction in the participants' level of discomfort experienced to week 4, where the minimum mean level of discomfort was experienced (Graph 4). A mean increase occurred at week 5, followed by a further increase at week 6.However, at week 6, participant 1 was the only participant to experience an increase in the level of discomfort, whereas, all the other participants experienced a reduced level of discomfort at week 6 compared to the level experienced at week 5. There was no significant difference seen in the level of discomfort experienced by the participants, over the osteopathic treatment period ($F=0.604$, $p=0.698$), but a moderate to large effect size was calculated ($f=0.39$).



Graph 4. Overall level of discomfort experienced in areas tender to touch or pressure.

Overall level of morning stiffness experienced from the time of waking up

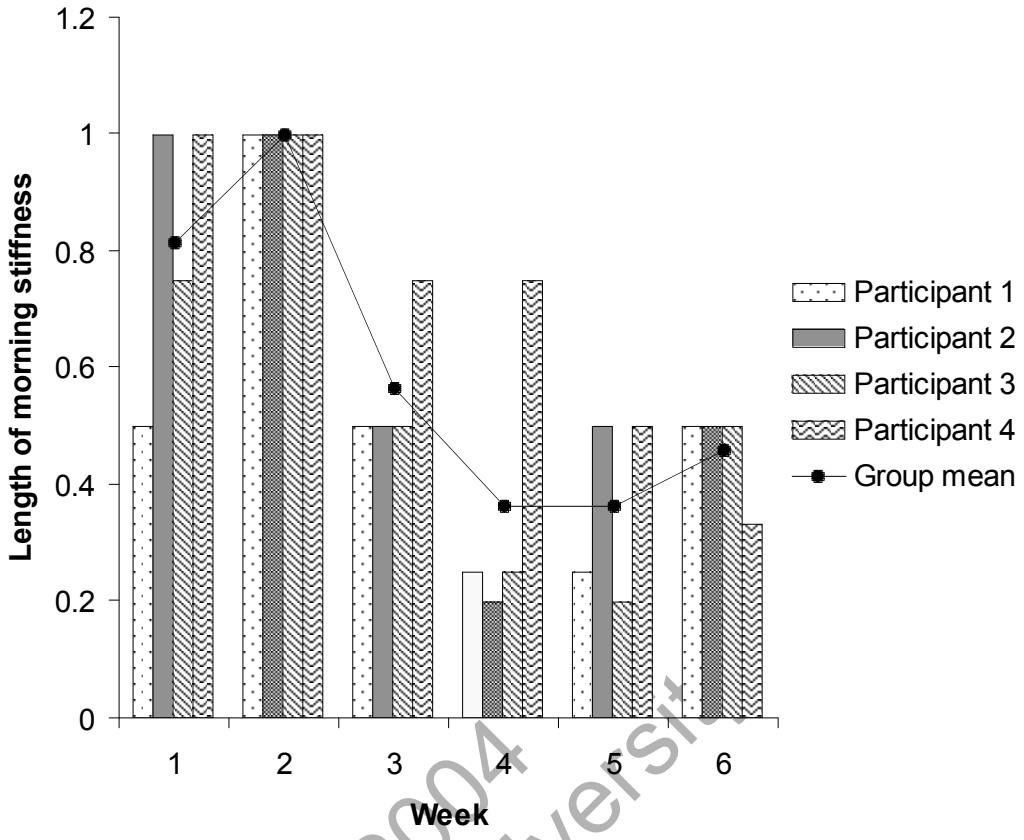
Generally, the mean level of morning stiffness experienced by the participants was relatively stable, with slight fluctuations (Graph 5). The lowest mean level of morning stiffness experienced was at week 3 and highest at week 1. The level of morning stiffness experienced by the participants over the treatment period was statistically insignificant ($F=1.262$, $p=0.323$). A large effect size was achieved ($f=0.56$).



Graph 5. Overall level of morning stiffness experienced.

Length of morning stiffness experienced

A mean increase in the participants' length of morning stiffness occurred at week 2, followed by a steep reduction in the level experienced to weeks 4 and 5 where length of stiffness remained relatively stable (Graph 6). A slight mean increase in the length of morning stiffness experienced occurred at week 6. The length of morning stiffness experienced by the participants was found to be significantly different between each of the osteopathic treatment sessions ($F=9.413$, $p=0.00$) Post-hoc analyses showed these differences to occur between weeks 1 and 4 ($p=0.016$), 1 and 5 ($p=0.016$), 2 and 3 ($p=0.019$), 2 and 4 ($p=0.001$), 2 and 5 ($p=0.001$), and 2 and 6 ($p=0.003$). A large effect size was achieved ($f=1.5$).



Graph 6. Length of morning stiffness experienced.

The greatest reductions achieved in the participants' symptoms was variable, but generally occurred at weeks 3 through to 6. Exacerbations of the participants' symptoms was also variable, but tended to occur at weeks 2, 5 and 6. The intensity of fatigue/tiredness, level of morning stiffness, and length of morning stiffness were the most common symptoms exacerbated at week 2. The level of neck, back or hip pain experienced, pain/swelling experienced, and discomfort experienced were the most common symptoms exacerbated at week 5. The level of pain/swelling experienced, discomfort experienced, and the level and length of morning stiffness experienced were the most common symptoms exacerbated at week 6.

SF-36

The results from the reported health transition scales were purposely omitted from the results section, as they measured change in health status over the past year, and our study was only over six weeks. The participants still completed the full survey, including the relevant reported health transition scale question, as omitting the relevant question in the questionnaire would have altered the validity of the questionnaire.

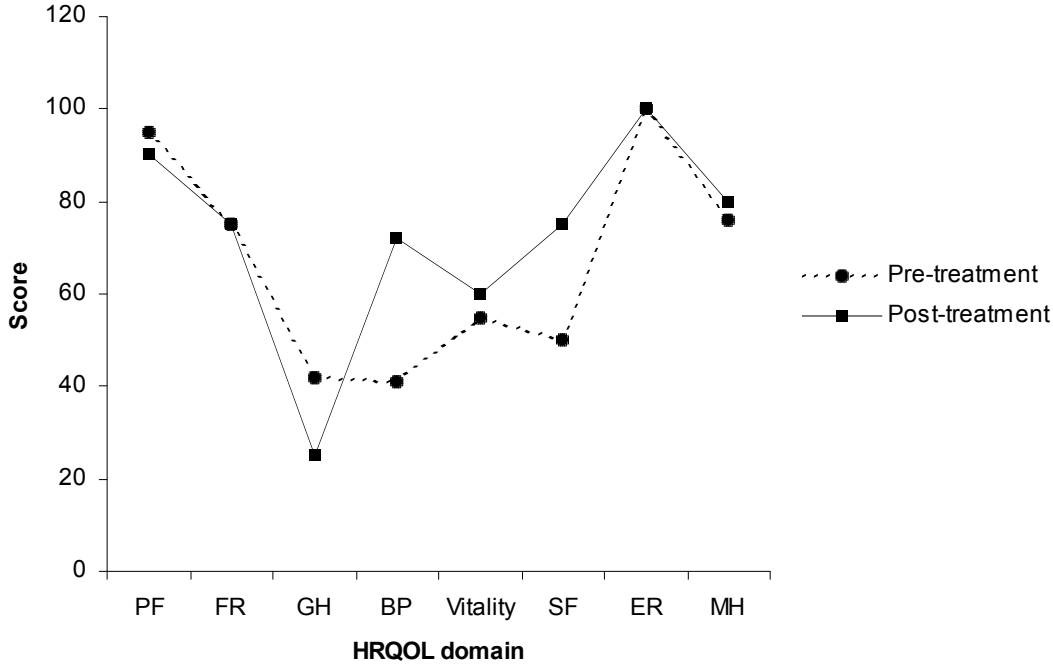
Participant 1 experienced improvements in bodily pain (BP), vitality, social functioning (SF), and mental health (MH), a decline in physical functioning (PF) and general health (GH), and no change in physical role (PR), and emotional role (ER) (Graph 7). Participant 2 experienced improvements in PF, PR, GH, BP, vitality and SF, a decline in MH, and no change in ER (Graph 8). Participant 3 reported a decline in PF, PR, BP, vitality, SF and MH, an improvement in GH, and no change in ER (Graph 9). Participant 4 experienced improvements in PF, BP, vitality, ER, and MH, a decline in PR and GH, and no change in SF (Graph 10).

Paired t-test calculations at weeks 1 and 6 (after osteopathic treatment intervention) indicate a mean improvement in the participants' vitality levels (-0.3), BP (-13.5), SF (-9.25) and ER (-8.5), and a mean decline in PF (3.75), PR (12.5), GH (3.75) and MH (5.0). The effects of osteopathic treatment on HRQOL in individuals with PsA was found to be statistically insignificant ($p>0.05$). Pre- post- effect sizes achieved were large for BP (d=-0.6) and ER (d=-0.6), and moderate for vitality (d=-0.3), PF (d=0.3), PR (d=0.4), GH (d=0.4), SF (d=-0.4) and MH (d=0.4). All 4

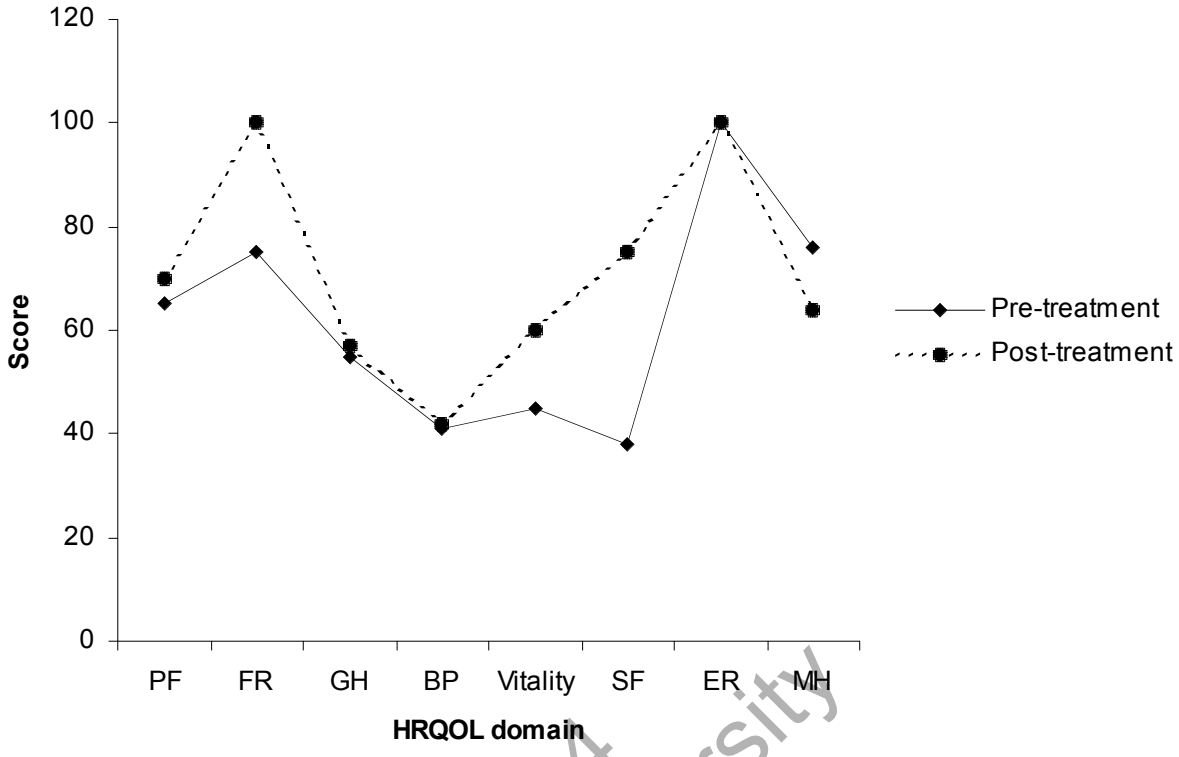
participants had no change in the reported health transition scale (d=0). These results are outlined in table 1.

Table 1. t-test summary table.

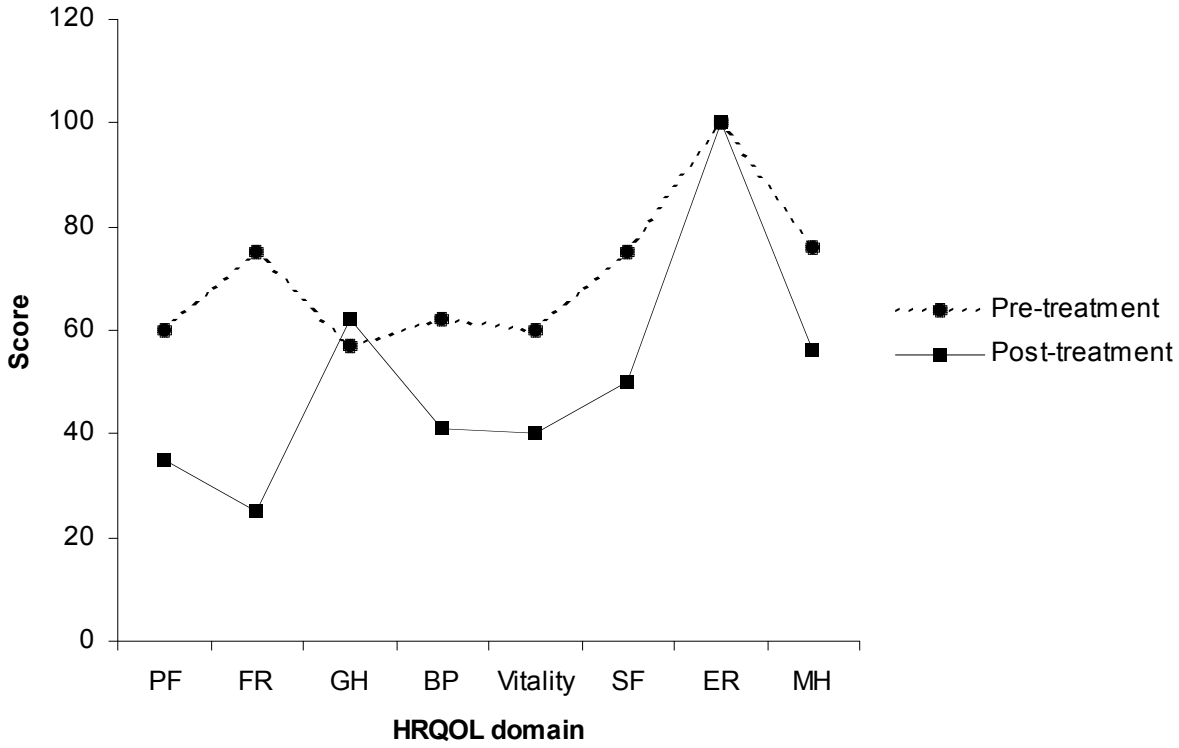
Measure	Mean (SD)	*t* value	*p* value	95% CI	Effect size (*d*)
Physical functioning					
Pre-treatment	72.5(15.55)	0.485	0.661	(-20.88, 28.38)	0.300
Post-treatment	68.75(23.9)				
Difference	3.75(15.48)				
Physical role					
Pre-treatment	68.75(12.5)	0.775	0.495	(-38.86, 63.86)	0.495
Post-treatment	56.25(37.5)				
Difference	12.5(32.27)				
General health					
Pre-treatment	54.0(8.52)	0.767	0.499	(-11.81, 19.3)	0.400
Post-treatment	50.25(16.99)				
Difference	3.75(9.78)				
Bodily pain					
Pre-treatment	46.25(10.5)	-1.078	0.360	(-53.37, 26.37)	-0.600
Post-treatment	59.75(15.97)				
Difference	-13.5(25.05)				
Vitality					
Pre-treatment	52.5(6.45)	-0.454	0.681	(-30.04, 22.54)	-0.300
Post-treatment	56.25(11.09)				
Difference	-3.75(16.5)				
Social functioning					
Pre-treatment	59.5(18.56)	-0.672	0.550	(-53.08, 34.59)	-0.400
Post-treatment	68.75(12.5)				
Difference	-9.25(27.55)				
Role-emotion					
Pre-treatment	83.25(33.5)	-1.000	0.391	(-35.55, 18.55)	-0.600
Post-treatment	91.75(16.5)				
Difference	-8.5(17.0)				
Mental health					
Pre-treatment	73.0(6.0)	0.757	0.504	(-16.03, 26.03)	0.400
Post-treatment	68.0(10.33)				
Difference	5.0(13.22)				



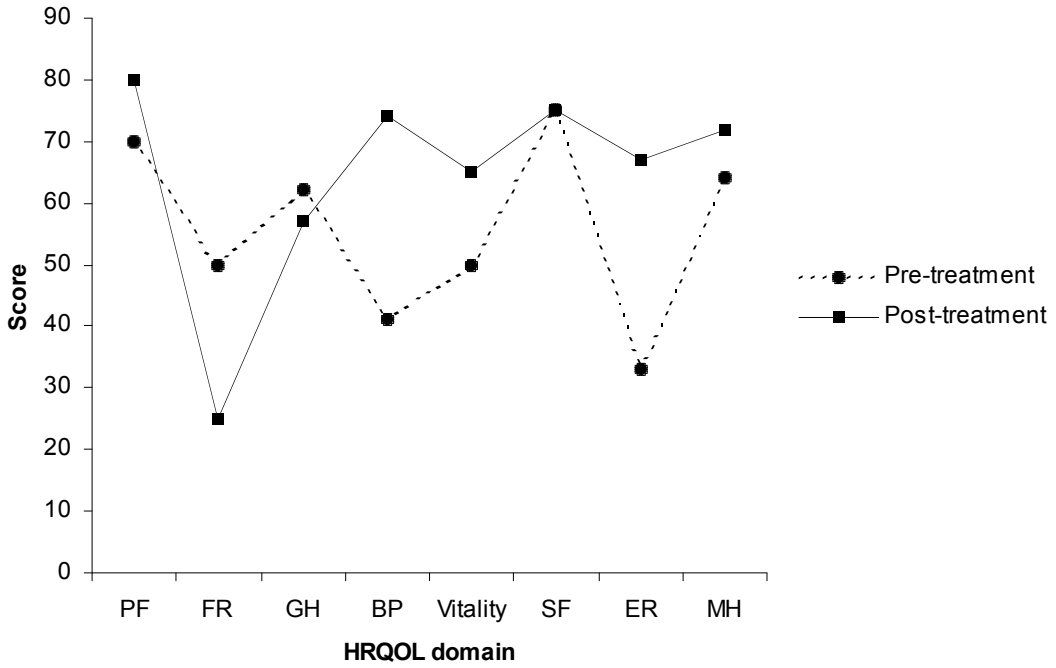
Graph 7. Participant 1 HRQOL scores pre-treatment and post-treatment.



Graph 8. Participant 2 HRQOL scores pre-treatment and post-treatment.



Graph 9. Participant 3 HRQOL scores pre-treatment and post-treatment.



Graph 10. Participant 4 HRQOL scores pre-treatment and post-treatment.

DISCUSSION

This study has demonstrated that osteopathic treatment significantly reduced the overall level of fatigue/tiredness, the overall level of pain/swelling in joints other than neck, back or hips, and the overall length of morning stiffness experienced by the participants with psoriatic arthritis. These positive results were also reflected in the large effect sizes achieved *f*=1.2, *f*=0.96, and *f*=1.5, respectively, which suggests that people with psoriatic arthritis could possibly benefit and receive some symptomatic relief in these symptoms if they receive osteopathic treatment.

Each of the participants reported moderate to high levels of fatigue throughout the treatment period, with a mean gradual reduction. Previous reports have also suggested that fatigue is a commonly reported complaint, and a major problem for people with arthritis.[21,29,40] Ward [29] investigated HRQOL in 157 AS patients and found that 54% reported poor sleep, and concluded that this was a major cause of fatigue, and efforts to improve sleep may be effective in reducing fatigue levels. Possibly, the osteopathic treatments benefited our participants by enabling them to have a better, less interrupted sleep (e.g. due to reduced pain levels) that resulted in a reduction in the amount of fatigue experienced. Furthermore, all participants experienced an exacerbation of their fatigue levels at week 2, which could have been contributed to by treatment (e.g. manual therapy and/or exercise prescription) [36, 41] an increase in disease activity, emotional factors, or other external factors (e.g. changes in whether and work related stresses, to name a few).

83.1% and 90.2% of AS patients considered pain and stiffness, respectively, major concerns,[29] and any relief in these symptoms would be beneficial for these patients. In our study, the statistical significant reduction in the overall level of pain/swelling in joints other than the neck, back or hip, and the reduction in length of morning stiffness is of importance, as people with PsA could gain some considerable beneficial relief from these highly concerning symptoms (with generalisation to PsA) with osteopathic treatment. Our findings support similar findings of reduced pain and swelling in AS participants after participants received a comprehensive home

physiotherapy treatment program, which saw improvements in mobility, swelling and reduced pain levels.[42]

The participants also experienced a mean gradual reduction in the overall level of neck, back or hip pain experienced, but this was statistically insignificant, even with a large effect size (f=0.6). The level of discomfort experienced (f=0.39) and the level of morning stiffness experienced (f=0.56) by the participants, also insignificant with moderate-large effect sizes, had a mean gradual reduction until weeks 4 and 5 where they increased in intensity until week 6. Although these symptoms of pain, discomfort, and level of morning stiffness did not show statistical significance, the tendency towards some improvement during the study period, along with moderate to large effect sizes achieved, are very encouraging for people with PsA who receive osteopathic treatment. A different study design with a larger number of participants could possibly be able to detect significant improvements in these symptoms as well.

The greatest reductions achieved in the participant's symptoms was variable, but generally occurred at weeks 3 through to 6, which suggests that several osteopathic treatments are required before any substantial symptomatic relief occurs in people with PsA. Participants also experienced occasional exacerbations of their symptoms at some stage during the study period, particularly at weeks 2, 5 and 6. However, it is difficult to say whether these exacerbations, like fatigue, were due to treatment effects, [36, 41] an increase in disease activity, [41] emotional factors, or other external factors.

At some weeks, all participants had an exacerbation of their symptoms in the same week, which suggests that possibly, these flare-ups were due to external factors such as a change in weather, or due to the initial shock of treatment, which possibly accounts for the increase in fatigue levels at week 2. Furthermore, all participants had an exacerbation of pain/swelling levels at week 6, which suggests that possibly emotional factors were involved e.g., knowing that the study was coming to an end, and making out that their symptoms were a lot worse than what they actually were, so they could receive further treatment. Participant 1 had an exacerbation of the majority of symptoms at week 6 compared to the level experienced at week 5, likely due to a confession to excessive alcohol consumption during that week. McDermaid and Mior,

[41] reported similar findings of exacerbations in participants with AS who had exacerbations due to chiropractic treatment. The authors reported that in their experience, the manipulation of inflamed joints may have provided short-term benefit, but typically exacerbated the symptoms hours later. In the present study, the BASDAI questionnaires were given to the participants to complete before the initial treatment and one week after their treatments, to try and avoid the measurement of this transitory exacerbation in their symptoms following manual therapy, that likely would have erroneously skewed the results. Completing the instruments a week after treatment would allow sufficient time for the joints to settle down. To further control for this, a more extensive study should include a control group.

Even though there were no statistically significant findings found for the effects of osteopathic treatment on HRQOL in people with PsA, there were still some clinically relevant findings with moderate-large effect sizes produced, that are encouraging. There was a mean improvement in the participants' vitality, BP, SF and ER. Effect size calculations show that a moderate effect size for vitality was produced (*d*=-0.3), a large effect for BP (*d*=-0.6), moderate for SF (*d* =-0.4) and large for ER (*d*=-0.6). Studies have shown [25, 26] that PsA patients have lower scores on HRQOL than do the general population, and that an improved HRQOL was experienced by arthritic patients, when offered osteopathic treatment, as opposed to pharmacological therapy.[16] The improvement seen in some of the HRQOL domains in the participants further supports Finley's [16] suggestions that osteopathic treatment can be beneficial in improving HRQOL in people with arthritis.

A mean reduction (or worsening) in the participants PF, PR, GH, and MH occurred, which negates positive findings received from other studies utilising the beneficial effects of manual therapy [16, 42] Effect size calculations indicate moderate effects for PF (*d* =0.3), PR (*d* =0.4), GH (*d* 0.4), and MH (*d* =0.4), which, although not benefiting the participants, suggests that treatment is having some form of effect.

Since HRQOL has been reported as being reduced in psoriatic arthritics, any improvements seen in any HRQOL item, even if insignificant, with moderate-large effect sizes, can be considered as being beneficial to that individual, and warrants further investigation.

Even though the general trends and effects have been the focus of discussion, it must be noted that not all of the participants' results fitted with the general trend of the groups findings, and this was a limiting factor. There was much variability amongst each of the participants (some reporting improvements, and some, a worsening), and it is difficult to say whether the findings from the study were due to the osteopathic intervention (real effects), the therapist-patient relationship, spontaneous remission, or random effects. Considering that multiple measures were taken over the six-week period, it is likely that these findings were due to real effects. Although, it is possible, considering the fluctuating nature of PsA, that at the time of outcome measurements, the participants may have been experiencing an unexpected flare-up and/or marked reduction in their symptoms/HRQOL, compared to the average severity for that week, therefore affecting the results. Perhaps, future research could look at the use of outcome measures at different phases throughout the study period and/or the incorporation of a control group.

Participant 3 experienced an improvement in all six symptoms reported on the BASDAI, however, reported no changes or a decline in all HRQOL scores, except for improvements in GH, possibly due to experiencing a high level of work related stress during the study period. This discrepancy again highlights the importance of using other measures e.g. functional measures, self-reporting measures (possibly looking at other external issues) in attempting to get a true indication of the effect of treatment.

Several factors need to be acknowledged that have limited the findings of this study. The most important limitation was the use of a small number of participants, that limited the generalizability of our results, as well as making it difficult for statistically significant results to be achieved. The moderate-large effect sizes produced suggest that osteopathic treatment is having some kind of effect on PsA individuals, thus warranting further research. Future research could utilise a larger number of participants, allowing for a higher possibility of valid and significant results to be achieved.

Another limitation was that the clinical course and the presentation of the disease, varied widely between each of the participants. The symptoms and HRQOL issues experienced, were a subjective experience to each of the participants, thus

accounting for the possible variability within the results. Furthermore, the measures used may not have covered all of the participants' presenting symptoms and HRQOL issues, or covered symptoms and areas of the body not applicable to that participant. The use of the BASDAI and SF-36, in the present study may be deemed inappropriate, even though these tools have been validated for PsA. In the light of this perhaps future research could use different outcome measures, or develop new measurement tools for the use in PsA.

Future studies could utilise an A-B-A research design where repeated measures (e.g. over several weeks) of the outcome variables (Pre-treatment, treatment-phase and post-treatment) are taken. Baseline measures are established so as to assess the stability of the condition prior to treatment intervention, and most importantly, to ensure that any change in symptoms can be more likely attributable to the intervention.[43] An intervention withdrawal phase could follow the baseline and treatment phases, so as to record whether the condition reverts back to baseline once treatment has ceased, thus showing the effectiveness of treatment.

CONCLUSION

The results of this study have demonstrated that osteopathic treatments may be capable of producing some symptomatic relief and improvements in HRQOL for people with psoriatic arthritis, with much variability in results between participants. Significant improvements were seen in the overall level of fatigue/tiredness, the overall level of pain/swelling in joints other than neck, back or hips, and the overall length of morning stiffness experienced by the participants. Non-significant mean improvements were seen in vitality, bodily-pain, social-functioning and emotional-role. However, these results are hampered by certain weaknesses within the study design; and the results so far suggest that further research is required.

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APPENDIX A

The Bath Ankylosing Spondylitis Disease Activity Index

BASDAI
The Bath Ankylosing Spondylitis Disease Activity Index

PLEASE PLACE A MARK ON EACH LINE BELOW TO INDICATE YOUR ANSWER TO EACH QUESTION, RELATING TO THE PAST WEEK

(1) How would you describe the overall level of fatigue/tiredness you have experienced?

NONE _____ **VERY SEVERE**

(2) How would you describe the overall level of AS neck, back or hip pain you have had?

NONE _____ **VERY SEVERE**

(3) How would you describe the overall level of pain/swelling in joints other than neck, back or hips you have had?

NONE _____ **VERY SEVERE**

(4) How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?

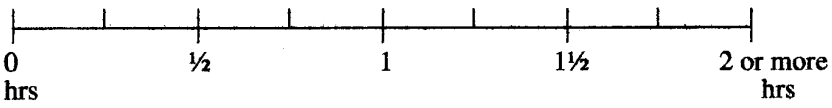
NONE _____ **VERY SEVERE**

(5) How would you describe the overall level of morning stiffness you have had from the time you wake up?

NONE _____ **VERY SEVERE**

(6) How long does your morning stiffness last from the time you wake up?

NONE _____ **VERY SEVERE**



APPENDIX B

SF-36 HEALTH SURVEY

INSTRUCTIONS: This questionnaire asks for your views about your health, how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent 1

Very good 2

Good 3

Fair 4

Poor 5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

Much better now than one year ago 1

Somewhat better now than one year ago 2

About the same as one year ago 3

Somewhat worse now than one year ago 4

Much worse now than one year ago 5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking **more than one kilometre**	1	2	3
h. Walking **half a kilometre**	1	2	3
i. Walking **100 metres**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

No bodily pain 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt down?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

(IQOLA SF-36 Standard Australia/New Zealand Version 1.0 - 7/94)

APPENDIX C

Consent Form for Participants Involved in Research
(Attach to Participant Information Statement)

CERTIFICATION BY PARTICIPANT:

I,_____

of _____

certify that I am at least 18 years old, and voluntarily consent to participate in the research project entitled: The Effects of Osteopathic Treatment on people with Psoriatic Arthritis. A Pilot Study, being conducted at Victoria University of Technology.

Investigator(s): Dr. Jim Kiatos.
Dr. Edwina Ryan.
Ms. Rebecca Wall.

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 Ms. Rebecca Wall.

and that I freely consent to participation involving the use of the following procedures on me:

- Soft tissue massage.
- Mobilisation techniques (eg, Manipulation and articulation).
- Muscle energy techniques.
- SF-36 Health survey.
- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).
- Relevant orthopaedic tests (ie, to exclude risks).

I certify that:

- I have received a Participant Information Statement.
- I understand the purpose and nature of my involvement.
- I understand the potential risks of my involvement which may include;

    - The temporary aggravation of my symptoms/complaint
    - Compromise of the major arteries in the neck that supply the brain (Vertebrobasilar insufficiency)
    - Compression of spinal cord/nerve roots
    - Bone fracture, due to reduced bone density and weakening
    - Embarrassment in taking my clothes off, and answering questions about my health
    - Disappointment if treatment is not working

- I understand the importance of the communication between my doctors and the investigators about my medication history and bone density status, and allow for this.
- I understand that it is important for me to answer the investigators questions to the best of my knowledge, especially concerning my health.
- I have had the opportunity to have any questions answered
- I have been informed that the information I provide will be kept confidential, and my identity will not be disclosed
- I understand that I can withdraw from the study at any time without explanation.
- I understand that if I refuse to consent, or if I withdraw from this study at any time without explanation, this will not jeopardise me in any way.
- I understand that I am entitled to consult Dr Mark Andersen, a registered psychologist, for counseling on 9919 5413, or my campus student counselor (if VU student) through Student Services on 9688 4418, for support if I wish to discuss any problems that may arise during my involvement in the study.

Signed: _____Date:_____

Witness other than the researcher:_____ Date:_____

Any queries about your participation in this project may be directed to the researcher Dr. Jim Kiatos ph: 03 9248 1191). 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 MC, Melbourne, 8001 (telephone no: 03-9688 4710).

APPENDIX D

PARTICIPANT INFORMATION STATEMENT

You are invited to participate in a Research Project titled:

The Effect Of Osteopathic Treatment On People With Psoriatic Arthritis. A Pilot Study.

What is this Information Statement?

The following pages contain information about a research project we are inviting you to take part in. The purpose is to clearly explain to you all the steps and procedures involved in this research project, and to provide information to help you decide whether or not you would like to take part in this research.

Please read the following information carefully. You are welcome to contact us if you wish to talk about the project, or ask any questions. When you are confident that you understand what the study is about, you can sign the consent form attached if you wish to take part.

What is the Research Project about?

If you have been diagnosed with psoriatic arthritis by a Rheumatologist, and are over the age of 18 years, you are invited to take part in this study. As a participant, you will remain anonymous, and will receive 5 osteopathic treatments, once a week for 5 weeks The duration of the study is 6 weeks. The treatments will be of no charge to you and will be conducted by an osteopath at the Victoria University Osteopathic Clinic, Level 4, 301 Flinders Lane.

The purpose of this study is to investigate whether osteopathic treatment will affect the presenting complaints of psoriatic arthritis (i.e., stiffness, tenderness, pain, and swelling of associated joints and soft tissue structures.) You will be required to report any changes in your presenting symptoms or behaviour (i.e., changes in pain and discomfort, stiffness, swelling, tiredness, mood, activity levels, problems with work or social activities, and other health related behaviours) by filling in surveys which will be provided at the beginning of each treatment session. The osteopath will then treat you, according to your presenting complaints with a variety of techniques. Some of the techniques that may be used by the osteopath include soft tissue massage and stretching, manipulation, and techniques that help mobilise the spine and other joints.

What is required of me to do to be in this research project?

As a participant, you will receive 5 osteopathic treatments, once a week for 5 weeks by an osteopath. The study is 6 weeks long.

In the initial treatment, the osteopath will take your full medical history, followed by a comprehensive examination of your problems associated with the arthritis. This initial treatment should last about 1 hour, and subsequent treatments will be of 30-minute duration. You will be required to report any changes in your presenting symptoms or

behaviour (i.e., changes in pain and discomfort, stiffness, swelling, tiredness, mood, activity levels, problems with work or social activities, and other health related behaviours) by filling in the questionnaires provided at the beginning of each of the treatment sessions. You will have a total of 8 surveys to complete over the 6 weeks, each taking approximately 30 seconds to 5 minutes to complete.

Before the first treatment at week 1, you will be required to fill out two surveys, the Bath Ankylosing Spondylitis Diseases Activity Index (or BASDAI for short), and SF-36 Health Survey Questionnaire. At weeks 2-4, you will receive a BASDAI before the commencement of each of the treatment sessions. At week 5, you will also receive a BASDAI to complete before the treatment commences, as well as an envelope containing a BASDAI and SF-36 for you to take home and complete at the same time next week. You will then be required to return them in the postage paid envelope that is supplied. You will not be required to come into the Student Osteopathic Clinic at week 6, as you will not receive a treatment this week. Any information that you provide will remain strictly confidential and in the hands of the investigators.

Is there likely to be a benefit to me?

Anecdotal evidence provided by patients and osteopaths, suggests that osteopathic treatment can be beneficial in reducing some of the presenting complaints (stiffness, pain, and swelling) of arthritis, as well as improving quality of life either alone, or in combination with more conventional medical treatment. However, there is a possibility that the treatment may actually aggravate your symptoms.

What are the possible risks and/or side effects?

There is a possibility that the treatment may temporarily aggravate your presenting symptoms. During the actual treatment you will be asked to provide ongoing feedback regarding your comfort levels. This will allow for the immediate cessation of the treatment in the event of any discomfort felt by you as well as the application of a gentler alternative treatment. If you are still experiencing discomfort after the alteration in treatment, and your symptoms become too much for you to cope with, you will be given the opportunity to review you desire to continue with treatment. 3-4 days following the treatment, the student investigator will call you to see how you are feeling and whether you have recovered after the last treatment session. If you are suffering a great deal of discomfort due to the last treatment, you will be asked if you still wish to participate in the study.

With some treatment techniques (e.g., manipulation) used in the neck (cervical spine) there is a potential risk that your major arteries to the head (the Vertebral arteries) may be stressed resulting in a condition known as vertebrobasilar insufficiency, where there is insufficient blood flow to certain parts of the brain. This may lead to a temporary reduction in blood flow to the brain resulting in symptoms such as dizziness, blurred vision, pins and needles, and weakness or in very rare cases stroke or death. However, these risks can be minimised by the routine use of screening examinations and thorough history taking by the osteopath, looking for any indications that may put you at risk before the introduction of these techniques.

There is also a possibility, due to the inflammatory nature of psoriatic arthritis, that the upper cervical spine ligaments may be affected, resulting in upper neck instability, and possible upper cervical spinal cord/nerve root compression with the use of end-range techniques. However, this is quite rare in people with psoriatic arthritis. You will be routinely screened for this instability, and any techniques that may compromise this area will not be used on you by the osteopath.

If you have been taking cortisone medication (e.g., containing Prednisolone, Hydrocortisone, Beclomethasone/Budesonside, Betamethasone, etc.) for a long-time, there is a possibility that you may have areas of reduced bone strength, and if a forceful technique (e.g., manipulation) was applied to this weakened bone, a fracture may occur. A letter requesting information regarding your bone density status will be sent by us to your doctor. In the event that this information is unavailable, you will be treated using gentler techniques. If you are concerned that you may have signs of bone weakening, due to long-term cortisone use or from other causes, you should speak to your doctor about the possibility of having bone density tests performed. If you are aware that you have signs of bone weakening, it is important that you notify us, so we can discuss with your doctor the extent of the problem.

What are the possible discomforts and/or inconvenience?

During the assessment, you are required to notify the osteopath about any illness/conditions that you have or have suffered from in the past, as well as your presenting complaints. If you feel uncomfortable or embarrassed about expressing the severity and/or nature of your symptoms, or anything else in your past medical history, you don't have to do so. But keep in mind that it is necessary for your safety, so the osteopath will know what she can or can't treat safely and effectively.

Furthermore, there is no need for embarrassment in expressing the severity and/or nature of your symptoms when filling out the provided questionnaires, as the information that you provide will remain anonymous, and strictly confidential.

As part of the treatment you will be required to disrobe down to your underwear and to wear a treatment gown provided, which may be embarrassing for some participants. However, this will be done in the privacy of the treatment room with out the presence of the osteopath. If this makes you uncomfortable you may discontinue with the study.

Some of the techniques that the osteopath may use to treat your symptoms, may actually aggravate your symptoms, making them worse. The techniques that will be used were chosen due to the effects of improving motion and soft tissue structures, not for inflicting pain. So some discomfort may be felt after the treatment, and possibly for a few days. If you are disappointed or unsatisfied with the treatment not working, and intensifying your symptoms, you can withdraw from the study. However, keep in mind that there is no published data regarding treatment outcomes, thus the treatment may not bring about any significant change in your condition.

In the unlikely event that you are injured in anyway during the treatment immediate treatment would be sought from one of the 1st aid qualified personal, on campus at the time of intervention.

What will be done to maintain confidentiality?

Any information obtained in connection with this study and that can identify you will remain confidential. Your name will not be required on the surveys or at the time of treatment. Each participant will be assigned a number code. The participant's names will be replaced by number codes, and will be used on files containing raw data and for electronic data entry. The number-name code will be stored separately in a locked cabinet in the principle investigators office. The surveys will be administered, collected and analysed by the student investigator. The treatment of the participant will be supervised by an osteopathic practitioner, Dr. Edwina Ryan. The investigators directly involved with the study will be the only people with access to the raw data and the database.

If your identity was established, and confidential information leaked about you (i.e., breaking of the patient/practitioner confidentiality agreement), you will be dropped from the study and any information obtained will be discarded and shredded.

The medical history, examination findings, and treatment that will be given to the you will be noted on a case history sheet, and will be provided to the appropriate parties in an event of trauma sustained to you, or by your or your doctors request.

If you are disappointed that the treatment is not working, or wish to discuss any problems that may arise form your involvement in the study you can make an appointment with Dr Mark Andersen, a registered psychologist, for counseling by calling 99195413. If you are a Victoria University student, instead contact your campus' student counselor through Student Services by calling 9688 4418.

What do I do if I am interested in taking part in the study?

If you are interested in taking part in this study, please contact the investigators on the number provided. An appointment will be made at this time. At this meeting you will have the opportunity to have any additional questions addressed. You will also be assured by the student investigator that participation is completely voluntary, strictly confidential, and that you are free to withdraw from the study at any time. You will be asked to complete and sign an informed consent form (see appendix F) if you wish to participate in the study. Once you have given your consent, the student investigator will ask you about what medications you are on, or have been taking, and for how long. This is of particular interest, for if, you have been taking cortisone medication long-term, there is the possibility, that you may have developed a reduced bone density which would contraindicate the use of a number of treatment techniques. If this is the case, a letter requesting information regarding your bone density status will be sent to your doctor. In the event that this information is unavailable, you will be treated using low force techniques.

Then finally, an appointment will be made for the initial treatment session.

I stress that your participation is completely voluntary, therefore, you are free to withdraw from the study at any time, if you are feeling uncomfortable with the treatment or the questions being asked. You may wish to discuss your participation with your family and with your doctor. You are welcome to contact us if you wish to talk about the project, or ask any questions.

Thank you for taking the time to read this Information Statement.

Any queries about your participation in this project may be directed to the researcher Dr. Jim Kiatos ph: 03 9248 1191). 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 MC, Melbourne, 8001 (telephone no: 03-9688 4710).

APPENDIX E

RAW DATA

Bodily pain

	wk1	wk6
1	41	72
2	41	52
3	62	41
4	41	74

General health

	wk1	wk6
1	42	25
2	55	57
3	57	62
4	62	57

Mental health

	wk1	wk6
1	76	80
2	76	64
3	76	56
4	64	72

Vitality

	wk1	wk6
1	55	60
2	45	60
3	60	40
4	50	65

Social functioning

	wk1	wk 6
1	50	75
2	38	75
3	75	50
4	75	75

Emotional role

	wk1	wk6
1	100	100
2	100	100
3	100	100
4	33	67

Reported health transition

	wk1	wk2
1	2	2
2	3	3
3	4	4
4	4	4

Physical function

	wk1	wk2
1	95	90
2	65	70
3	60	35
4	70	80

Discomfort

week	score
1	5
1	1.8
1	2.2
1	1.5
2	3.5
2	1
2	2
2	1.3
3	1.6
3	1.5
3	1.5
3	1
4	1.7
4	0.2
4	1.4
4	1.2
5	4.1
5	1.9
5	1.5
5	1.1
6	6.35
6	0.6
6	1.6
6	1

Fatigue

Week	score
1	2.8
1	5.5
1	6
1	5
2	5.5
2	7.4
2	6.5
2	6
3	4.4
3	5.6
3	5
3	5.5
4	3.9
4	3
4	4
4	5
5	1.6
5	6
5	5
5	4
6	1.25
6	1.2
6	1.2
6	3.9

Pain

week	score
1	7.4
1	2.4
1	6
1	2
2	5.3
2	0
2	4
2	1
3	2
3	2.7
3	4.5
3	1.5
4	0.6
4	0.8
4	3.5
4	1
5	0.5
5	3.5
5	3.4
5	0.5
6	2.9
6	0

6	3
6	0

Pain/swelling

Week	score
1	3.25
1	4.1
1	5
1	5
2	6
2	1.8
2	4
2	3.5
3	1.4
3	1.8
3	2.5
3	2
4	0.5
4	1.2
4	2
4	1.3
5	3.2
5	1
5	2.1
5	1.5
6	8.6
6	2.4
6	3
6	4

Length morning stiffness

Week	score
1	0.5
1	1
1	0.75
1	1
2	1
2	1
2	1
2	1
3	0.5
3	0.5
3	0.5
3	0.75
4	0.25
4	0.2
4	0.25
4	0.75
5	0.25
5	0.5
5	0.2

5	0.5
6	0.5
6	0.5
6	0.5
6	0.33

Level of morning stiffness

Week	score
1	6.15
1	1.8
1	4
1	2
2	4.4
2	3.4
2	3
2	3
3	2.5
3	1.5
3	2.5
3	1.9
4	3.1
4	3.5
4	3
4	2
5	2.4
5	1.9
5	2
5	3.3
6	3.35
6	2.3
6	2.5
6	3