

The effect of home-exercise with and
without additional osteopathic treatment
for those with shoulder impingement
syndrome

Tasman Darragh

A research project submitted in partial fulfilment of the requirements
for the degree of Master of Osteopathy
Unitec Institute of Technology, 2011



Declaration

Name of candidate: Tasman Darragh

This Research Project entitled “The effect of home-exercise with and without additional osteopathic treatment for those with shoulder impingement syndrome” is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

Candidate’s declaration

I confirm that:

- This Research Project represents my own work;
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

Research Ethics Committee Approval Number: 2010-1099

Candidate Signature:

Date:

Acknowledgements

I would like to thank my supervisors Rob Moran and Jamie Mannion who have provided me with so much support during this research project.

Thank you to all the participants for their willingness and time.

Finally, thank you Karen Darragh, my family and classmates for the huge amount of support and patience shown over the years.

Contents

Declaration	2
Acknowledgements	3
Contents	4
Introduction to Thesis	8
Section 1: Literature Review	10
1. Introduction	11
2. Shoulder Impingement Syndrome	12
2.1 Aetiology.....	12
2.2 Clinical Presentation	13
2.3 Prevalence of Shoulder Impingement Syndrome	13
2.4 Diagnosis of Shoulder Impingement Syndrome	14
2.5 Management and Treatment of Shoulder Impingement Syndrome	15
3. Exercise Prescription	17
3.1 Supervised Exercise	18
3.2 Supervised Exercise vs Control	20
3.3 Home-exercise vs Control.....	21
3.4 Home-Exercise vs Supervised Exercise	23
4. Manual Therapy.....	25
4.1 High-Velocity Low-Amplitude Thrust	25
4.2 Trigger Points.....	26
4.3 Osteopathic Treatment	27
5. Exercise Prescription combined with Manual Therapy.....	30
5.1 Introduction of an Active and Passive Treatment Model	30
5.2 Exercise Prescription combined with a Single Manual Technique.....	31
5.3 Exercise Prescription combined with a Comprehensive Manual Therapy Treatment.....	33
5.4 Exercise Prescription with and without Manual Therapy	34

5.5 Summary of Exercise Prescription combined with Manual Therapy	35
6. Conclusion	37
7. References	38
Section 2: Report of Recruitment	50
Introduction to Report of Recruitment	51
1. Methodological Considerations – Research Design	51
1.1 Comparison of Randomised Controlled Trial and Single System Research Design	51
1.2 Limitations of the SSRD	53
2. Recruitment Methods	54
2.1 Posters and Flyers.....	54
2.2 Online Advertising	56
2.3 Editorial.....	57
2.4 Initial Screening Process Prior to Assessment.....	57
3. Results of Recruitment and Advertising.....	58
3.1 Results of Recruitment	58
3.2 Results of Advertising	59
4. Discussion	61
4.1 Changes in Experimental Design and Reporting	61
4.2 Final Form of Reporting of Study.....	61
5. Conclusion	62
6. References	63
Section 3: Manuscript	65
1. Abstract.....	67
2. Introduction.....	68
3. Methods.....	71
3.1 Design	71
3.2 Participants.....	72

3.3 Outcome Measures	74
3.4 Intervention	76
3.5 Data Analysis.....	78
4. Results.....	79
4.1 Shoulder Pain and Disability Index	79
4.2 Disabilities of the Arm, Shoulder and Hand Outcome Measure	79
4.3 Numeric Pain Rating Scale	80
4.4 Self-reported Adherence	81
5. Discussion	82
5.1 Overview.....	82
5.2 Home-exercise	82
5.3 Home-exercise vs Supervised Exercise.....	83
5.4 Adherence to Home-exercise	83
5.5 Exercise Prescription combined with Manual Therapy.....	84
5.6 Clinical Benefit of Exercise Prescription combined with Manual Therapy	84
5.7 Internal Validity	85
5.8 External Validity.....	86
5.9 Future Research.....	87
6. Conclusion	88
7. References	89
8. Figures.....	99
9. Appendix of Manuscript	109
Home-exercise Program	109
Osteopathic Treatment	111
Section 4: Appendices.....	113
Appendix A: Recruitment Poster and Flyer	114
Appendix B: Editorial	117
Appendix C: Exercise Diary	119
Appendix D: Ethics Approval	123

Appendix E: Participant Information Sheet.....	125
Appendix F: Consent Form	131
Appendix G: <i>Manual Therapy</i> guide for authors.....	134

Introduction to Thesis

Shoulder disorders are a common presentation to healthcare professionals (Bot et al., 2005), with the most frequent diagnosis that of shoulder impingement syndrome (van der Windt, Koes, de Jong, & Bouter, 1995). Shoulder impingement syndrome occurs when structures within the subacromial space become compressed between the head of the humerus and the coracoacromial arch (Bigliani, Ticker, Flatow, Soslowky, & Mow, 1991; Michener, McClure, & Karduna, 2003) and is associated with the development of bursitis, rotator cuff tears and tendinopathy (Valadie III, Jobe C, Pink, Ekman, & Jobe W, 2000). Current evidence-based clinical practice guidelines recommend a conservative approach to the treatment of shoulder impingement (The Accident Compensation Corporation, 2004) including the use of exercise prescription and there is 'moderate' evidence that the addition of manual therapy to exercise prescription provides superior benefits over exercise prescription alone (Kromer, Tautenhahn, de Bie, Staal, & Bastiaenen, 2009).

Osteopathy uses many manual therapeutic techniques and has been shown to be of clinical benefit for several musculoskeletal disorders including neck pain (Fryer, Alvizatos & Lamaro, 2005) and lower back pain (Licciardone, Brimhall, & King, 2005). Musil (2006) evaluated the effectiveness of osteopathic treatment for shoulder impingement syndrome and although the results were promising the study contained weaknesses in reporting of methods and results which threaten the validity of the findings. There is clearly a need for further investigation into the effectiveness of osteopathic treatment for shoulder impingement. Therefore the aim of the case series in this thesis is to report the outcomes of a home-exercise program used alone and combined with a semi-standardised osteopathic treatment plan and thereby further the evidence for osteopathy as a treatment option for shoulder impingement syndrome.

This thesis is arranged in four sections. Section 1 is a literature review that will describe shoulder impingement syndrome and provide a critical review of the current evidence

for the use of exercise prescription, manual therapy, and osteopathy for the treatment of shoulder impingement syndrome. Section 2 is a report of the difficulties faced during the recruitment phase of this study that led to a change of the design and reporting of methods and results. Section 3 is a manuscript reporting the main findings of the investigation and is formatted in accordance with submission requirements of the *Manual Therapy* journal. Section 4 (Appendices) contains information not reported in Section 3, as well as documentation of ethics approval.

Section 1: Literature Review

1. Introduction

Shoulder impingement syndrome is a common presentation to both general medical practice (Bot et al., 2005) and practitioners of manual therapy (Pribicevic, Pollard & Bonello, 2009). Shoulder impingement causes pain and loss of function and has the ability to reduce an individual's quality of life and work status (Chipchase, O'Connor, Costi, & Krishnan, 2000). Current evidence-based clinical guidelines recommend conservative non-operative treatment of shoulder impingement with exercise prescription and simple analgesics (The Accident Compensation Corporation, 2004), and there is emerging evidence for the use of manual therapy as an adjunct to exercise prescription (Kromer et al., 2009). Osteopathy, a form of manual therapy, is associated with clinical improvements for several musculoskeletal disorders including neck pain (Fryer et al., 2005) and lower back pain (Licciardone et al., 2005). As primary healthcare providers in New Zealand, osteopaths manage musculoskeletal disorders yet there is limited evidence for the use of osteopathy in the treatment of shoulder impingement syndrome.

This literature review defines shoulder impingement syndrome and describes the effect of shoulder impingement syndrome on a person's quality of life. This review explores the current treatment options for shoulder impingement including activity modification, corticosteroid injection and surgery, before critically analysing the current literature relating to exercise prescription and manual therapy. Finally this review considers the current evidence for osteopathic treatment of shoulder impingement syndrome including a critical analysis of the one major study of osteopathy for this condition.

2. Shoulder Impingement Syndrome

Shoulder impingement syndrome, or more specifically subacromial impingement syndrome, is the mechanical compression of structures within the subacromial space (Bigliani et al., 1991) between the head of the humerus and the coracoacromial arch during gleno-humeral joint elevation (Michener et al., 2003). Structures that may become impinged within the subacromial space are the subacromial and subdeltoid bursa, the tendons of the rotator cuff muscles, the long head of biceps brachii muscle, and the superior capsule of the glenohumeral joint (Lewis, Green, & Dekel, 2001). Repetitive micro-trauma through mechanical compression to soft tissues within the subacromial space leads to pain and functional disability of the shoulder complex (Chipchase et al., 2000). Although not considered by some as a diagnosis in itself (Brukner & Khan, 2009), the repetitive mechanical irritation of the rotator cuff and other structures is thought to lead to bursitis, tendinitis, and rotator cuff tendinopathy (Valadie III et al., 2000).

2.1 Aetiology

Although the resultant inflammation and pain of shoulder impingement is caused by repetitive irritation of subacromial structures, the actual aetiology of impingement is complex. Contributors to the development of impingement have been reported to include: altered co-activation of the rotator cuff muscles (Diederichsen et al., 2009, Lewis, Wright, & Green, 2005; Myers, Hwang, Pasquale, Blackburn, & Lephart, 2009); tightness within the gleno-humeral capsule (Hjelm, Draper, & Spencer, 1996); altered scapular posture resulting in altered biomechanics of the shoulder girdle during arm elevation (Ludewig & Cook, 2000); late recruitment of scapular stabilising muscles during arm elevation (Moraes, Faria, & Teixeira-Salmela, 2008); forward head posture and poor thoracic extension (Lewis et al., 2001); and altered morphology of the acromion (MacGillivray, Fealy, Potter, & O'Brien, 1998).

2.2 Clinical Presentation

Shoulder impingement syndrome presents as pain localised to the antero-lateral humerus which often radiates into the lateral arm (Koester, George & Kuhn, 2005). People complain of pain primarily during activities involving use of the hands above shoulder level and when lying on the affected shoulder (Lewis et al., 2001). Functional ability of the shoulder can be reduced, with the pain and loss of function reported to reduce a person's quality of life and work status (Chipchase et al., 2000). Chipchase et al. reported 73% of people with a diagnosis of shoulder impingement felt unable to return to fulltime work because of their shoulder pain and disability.

2.3 Prevalence of Shoulder Impingement Syndrome

Shoulder pain is a common complaint to healthcare professionals. In a systematic review of the literature involving 18 studies from the United Kingdom, United States, Scandinavia, Cuba, South Africa, Spain, and Nigeria, point prevalence of shoulder pain within the general population was reported to range from 6.9% to 26% and lifetime prevalence from 6.7% to 67% (Luime et al., 2004). Bot et al. (2005) reported the incidence of shoulder complaints within Dutch general practices to be 19 per 1000 visits per year. In another study of general healthcare practices, almost half those with shoulder complaints were given a diagnosis of shoulder impingement (van der Windt et al., 1995). The prevalence of shoulder impingement syndrome as a presenting complaint to manual practitioners is less known. Pribicevic et al. (2009) conducted a survey to measure the prevalence of shoulder pain as a presenting complaint in chiropractic practices in New South Wales, Australia. Of 1037 surveys mailed, responses were received from 192(21%) practices. Shoulder pain was reported to account for 12% of presentations to chiropractic practices and of those, 44% were diagnosed with shoulder impingement. In an audit conducted by a private osteopathic practice only 1% of new patients presented with shoulder pain, however, no information was given about a specific diagnosis (McIlwraith, 2003).

2.4 Diagnosis of Shoulder Impingement Syndrome

In clinical practice the Neer, Hawkins, and painful arc tests are commonly used physical examination procedures to diagnose shoulder impingement syndrome (Park, Yokata, Gill, El Rassi, & McFarland, 2005; Valadie III et al., 2000) and are reported to have a high intra- and inter-examiner reliability (Johansson and Ivarson, 2009). The Neer test involves full passive forward elevation of the shoulder until the patient reports pain (Park et al., 2005), whilst the Hawkins test combines forward flexion of the gleno-humeral joint to 60° combined with full internal rotation (Tucker, Taylor, & Green, 2011). Reproduction of familiar pain in the shoulder indicates shoulder impingement syndrome (Valadie III et al., 2000). The painful arc test is described as active elevation of the arms in the scapular plane (Park et al., 2005), with pain indicative of shoulder impingement syndrome experienced between 60° and 120° of abduction (Calis M, Akgun, Birtane, Karacan, Calis H, & Tuzun, 2000; Cloke, Lynn, Watson, Purdy, Steen, & Williams, 2008). The Neer, Hawkins and painful arc tests have a sensitivity of 88%, 92%, and 32% respectively (Calis et al., 2000). Although the painful arc test has a low sensitivity, it has a high specificity of 80%, compared to the Neer test at 30%, and the Hawkins test at 25% (Calis et al., 2000).

Although physical tests are a valid tool for diagnosing shoulder impingement in the clinical setting they are not sufficient in making a definitive tissue diagnosis. Therefore, the use of imaging techniques should be considered and may help the clinician make a more specific soft-tissue diagnosis (Mulyadi, Harish, O'Neill, Rebello, 2009). Ultrasound is useful in measuring the diameter of the subacromial space in those with signs of shoulder impingement (Seitz & Michener, 2011), while magnetic resonance imaging may detect damage to soft-tissues (Dinnes, Loveman, McIntyre, & Waugh, 2003). Furthermore, plain film radiographic assessment can investigate acromion morphology using the supraspinatus outlet view (Bigliani et al., 1991).

2.5 Management and Treatment of Shoulder Impingement Syndrome

In New Zealand, the Accident Compensation Corporation (ACC) has published an evidence-based clinical practice guideline concerning the diagnosis and management of soft-tissue injuries and related disorders of the shoulder (The Accident Compensation Corporation, 2004). The guideline, prepared in consultation with a group of specialists involved in the management of shoulder injuries, recommends a conservative non-operative approach to treatment if shoulder impingement is suspected. Non-operative treatment includes a combination of pharmaceutical analgesics, modification of daily activities which may predispose to or maintain the injury, rehabilitation of the shoulder using supervised exercise, and physical therapy. In certain cases corticosteroid injection into the subacromial space may be justified and has been shown to improve function (Karthikeyan, Kwong, Upadhyay, Parsons, Drew, & Griffin, 2010) and pain (van der Windt, Koes, Deville, Boeke, de Jong, & Bouter, 1998) in those with shoulder impingement, although questions have been raised about its long term benefit (Grant, Arthur, & Pichora, 2004). Following 6 months of non-operative treatment it is recommended that a referral be made to an orthopaedic specialist (The Accident Compensation Corporation, 2004) for the consideration of surgery (Brox et al., 1999).

Surgery, using both open and arthroscopic decompression of the subacromial space, has been demonstrated to reduce symptoms of pain and improve functional measures during daily activities in patients with shoulder impingement syndrome (Andersen, Sojbjerg, Johannsen, & Sneppen, 1999; Brox et al., 1999; Haahr et al., 2005; Husby, Haugstvedt, Brandt, Holm & Steen, 2003; Spangehl, Hawkins, McCormack & Loomer, 2002), with little difference in outcome reported between the two forms of surgery (Husby et al., 2003). Surgery has also been shown to produce similar reductions in pain and improved functional status when compared against supervised exercise (Brox et al., 1999; Haahr et al., 2005). It does, however, remain unclear as to who should be selected for surgical treatment (Haahr et al., 2005) although a course of conservative treatment (Gebremariam, Hay, Koes, & Huisstede, 2011) including supervised exercise

(The Accident Compensation Corporation, 2004; Brox et al., 1999) is generally recommended.

In summary, non-operative treatment of shoulder impingement syndrome typically includes a combination of rest, advice on activity modification, anti-inflammatory medication, simple analgesics, heat packs, exercise prescription, manual therapeutic techniques such as soft-tissue mobilisation (The Accident Compensation Corporation, 2004; Conroy & Hayes, 1998). In some cases the administration of a corticosteroid injection into the subacromial space may be of clinical benefit (Karthikeyan et al., 2010; van der Windt et al., 1998) and surgery if non-operative treatment fails (Brox et al., 1999).

3. Exercise Prescription

Although there are a range of therapies for the treatment of shoulder impingement syndrome including acupuncture (Guerra de Hoyos et al., 2004) and therapeutic ultrasound (Santamato et al., 2009), exercise prescription and manual therapy seem to be most popular. Therefore sections 3 to 5 of this literature review will focus primarily on the role of exercise prescription and manual therapy, including osteopathy, for the treatment of shoulder impingement syndrome.

The treatment of shoulder impingement with exercise prescription has been extensively researched in the literature. Exercise prescription is a common and recommended initial treatment for shoulder impingement syndrome (The Accident Compensation Corporation, 2004; Brox et al., 1999), although two systematic reviews in which exercise prescription is analysed have suggested further high-quality trials are required to justify exercise as the initial treatment (Grant et al., 2004; Kromer et al., 2009). A large number of objectives for exercise prescription have been described in the literature with authors commonly adopting a combination of exercise interventions. Exercises described in the literature have addressed a range of exercise combinations to address: altered muscular activity of the rotator cuff; correct function of the scapular stabilisers; spasm of shoulder girdle musculature; restriction of the gleno-humeral joint capsule; restrictions in normal range of motion of the shoulder girdle; promotion of proper scapular kinematics during arm elevation; posture of the thoracic spine and shoulder girdle; nutrition of the rotator cuff; and centering of the humeral head within the glenoid fossa (Andersen et al., 1999; Bang & Deyle, 2000; Brox et al., 1999; Cloke et al., 2008; Conroy & Hayes, 1998; Cummins, Sasso, & Nicholson, 2009; Dickens, Williams, & Bhamra, 2005; Haahr et al., 2005; Kachingwe, Phillips, Sletten, & Plunkett, 2008; Ludewig & Borstad, 2003; Morl, Matkey, Bretschneider, Bernsdorf, & Bradl, 2010; Musil, 2006; Roy, Moffet, Hebert, & Lirette, 2009; Walther, Werner, Stahlschmidt, Woelfel, & Gohlke, 2004). This review will focus on the use of both supervised exercise and unsupervised home-exercise prescription for the treatment of shoulder impingement syndrome.

3.1 Supervised Exercise

Weakness and altered muscle activity of the rotator cuff and muscles of scapular stabilisation have been reported in people with shoulder impingement syndrome (Diederichsen et al., 2009; Leroux, Codine, Thomas, Pocholle, Mailhe, & Blotman, 1994; Ludewig & Cook, 2000), with strengthening exercises prescribed to improve altered muscle activity. Morrison, Frogameni & Woodworth (1997) sought to measure the effect of 6 weeks of standardised, supervised strengthening of the rotator cuff for the treatment of shoulder impingement. A retrospective study design was used, with the time period spanning from 1985 to 1991, and consisted of a large participant group ($n=636$ shoulders). The authors reported 67% of participants achieved a “satisfactory result” on the Shoulder Rating Scale of the University of California which measures pain intensity, function, active range of motion, and strength. A “satisfactory result” was determined in those participants who achieved a “good” or “excellent” score, or greater than 21 on the 35-point scale. The results of the study may be biased in favour of the intervention because of incomplete follow up. Just 75% of participants were available for physical examination at follow-up. The remaining participants were contacted by telephone with data collected for levels of pain intensity, level of activity, and work status. No information was gathered for active range of motion and strength and it was not explained how this was interpreted within the shoulder rating scale. Following the 6-week supervised exercise phase the reporting of the continuing intervention became vague. Participants were asked to continue the exercises at home until the pain had ceased for a period of 4 weeks. In this way the actual intervention period for each participant was not consistent. This strategy makes it difficult to evaluate the efficacy of the intervention as the intervention dose varied between participants. The follow-up period was also inconsistent between participants with follow-up measurements carried out over periods ranging from 6 to 81 months. This variability in follow-up time introduces bias as resolution of symptoms could occur in 6 months for some participants, or over a period of 6-7 years for others. The methodological issues of intervention dose and measurement bias reported in this study make it challenging to ascertain any firm conclusions in regards to the efficacy of

supervised exercise prescription for the treatment of shoulder impingement syndrome.

Altered muscle function in the rotator cuff group has been considered to be a major factor in the development of shoulder impingement (Diederichsen et al., 2009, Lewis et al., 2005; Myers et al., 2009). This has provided a clinical rationale for the large number of exercise programs containing rotator cuff strengthening exercises found in the literature. There is, however, a tendency for strength to be used as a generic term for muscle function, yet clinical outcome measures of pain and function have been shown to improve without concurrent improvements in shoulder strength (Bang & Deyle, 2000; Haahr et al., 2005; Lombardi, Magri, Fluery, da Silva, & Natour, 2008; Roy et al., 2009). This may be explained by the findings of Erol, Ozcakar, & Celiker (2008) who measured peak torque in participants with and without shoulder impingement. The authors reported little difference in shoulder strength between participants with and without shoulder impingement, raising questions about the role of shoulder strength as a causative factor in the development of shoulder impingement syndrome. Altered muscle activity patterns (Diederichsen et al., 2009; Moraes et al., 2008) and shoulder kinematics (Ludewig & Cook, 2000) rather than muscle strength may be a more appropriate focus for measuring muscle function following exercise prescription.

During the treatment phase of a single-system study by Roy et al. (2009), great importance was placed on improving scapular kinematics rather than absolute strength of shoulder musculature. Over a 4-week intervention period eight participants received 12 supervised sessions with a physiotherapist. The treatment consisted of exercises aimed at promoting control of the scapula during shoulder elevation in the frontal, sagittal and scapular planes of motion. Once the physiotherapist observed satisfactory scapular control participants progressed to strengthening exercises for the rotator cuff and scapula-thoracic muscles although the authors reported scapular control exercises were predominantly used during the intervention phase. At the conclusion of the intervention all participants achieved statistically significant

decreases in pain and disability using the shoulder pain and disability index (SPADI). The average reduction was 36 points on the 130-point index, well over the 13-point shift reported to represent a minimally clinically important difference (MCID) for the SPADI (Vaughan & DiVenuto, 2004). Pain present during active flexion and abduction was also measured, with only one participant reporting pain at the conclusion. As in other studies (Bang & Deyle, 2000; Haahr et al., 2005; Lombardi et al., 2008) little improvement was demonstrated for measurements of strength following exercise prescription. Only one participant showed statistically significant improvements in strength during active abduction, while three participants achieved this for active lateral rotation. The lack of improvement in strength measurements reported in this study may be explained by the intervention consisting primarily of scapular control exercises rather than strengthening exercises. Although strength was largely unaffected, the authors reported improved scapular kinematics in over half the participants in the motions of posterior tilt, lateral rotation, and protraction. The improved motion in these ranges may explain the improvement in pain and disability scores due to the role of altered scapular kinematics in the development of shoulder impingement (Ludewig & Cook, 2000).

3.2 Supervised Exercise vs Control

Using a randomised controlled trial (RCT), Lombardi et al. (2008) carried out a supervised strengthening exercise program to muscles of the gleno-humeral joint, including muscles of the rotator cuff, for the treatment of shoulder impingement. The study involved two groups of 30 participants diagnosed with shoulder impingement. Results of an experimental group were compared against a control group receiving no treatment. Participants in the experimental group received 2 treatments per week over an 8 week period. Clinical outcome measures were: a 10cm visual analogue scale (VAS) for pain at rest and with shoulder movement; function during activities of manual labour and activities of daily living using sections 2 and 3 of the disabilities of the arm, shoulder and hand (DASH) outcome measure; quality of life using the SF-36; shoulder strength; and active range of motion of the shoulder. Following the

intervention phase the experiment group had statistically significant reductions in pain at rest ($p=0.001$), pain with movement ($p=0.001$), DASH 2 ($p=0.007$), and DASH 3 ($p=0.013$) compared to the control group. In the experimental group a reduction of $1.8 \pm 2.3\text{cm}$ was observed for pain at rest with a 'moderate' effect size of $d=0.80$ (Hopkins, 2010).¹ Pain with movement reduced by $2.2 \pm 1.5\text{cm}$ with a 'large' effect size of $d=1.39$. DASH 2 and 3 also showed reductions with effect sizes of $d=0.87$ and $d=0.59$ respectively. Participants in the experimental group demonstrated significantly greater improvements in abduction and extension range of motion over those in the control group ($p=0.001$ and 0.032 respectively), however no significant difference was found between groups for flexion and medial/lateral rotation. As impingement of the shoulder occurs during shoulder abduction (Valadie III et al., 2000) an improvement in the abduction plane of motion reported by the authors may explain the reduction in pain symptoms and the greater degree of function ability during both laborious and daily activities. Although the experimental group were prescribed strengthening exercises, there was little difference found between groups in regards to the strength of the shoulder girdle, a finding reported by other authors (Bang & Deyle, 2000; Haahr et al., 2005; Roy et al., 2009). Statistically significant improvements in strength ($p=0.05$) were only demonstrated for extension in the experimental group compared to the control group. The quality of reporting in the study by Lombardi et al. (2008) was satisfactory in terms of what exercises were prescribed, the time frame for the intervention phase of the experiment, and the follow-up period over which measurements were taken. By specifying a common follow-up period for each participant the authors minimised the measurement bias that was evident in the earlier study by Morrison et al. (1997).

3.3 Home-exercise vs Control

A recent trend in shoulder impingement syndrome research has been the investigation of home-exercise prescription for the treatment of shoulder impingement. The study

¹ Effect sizes reported in this section were not reported by Lombardi et al. (2008) in the text but were calculated by the author based on the results presented in the article.

of home-exercise is of research interest as it may show whether patients need attend supervised sessions to gain clinically beneficial results from exercise prescription, which may possibly reduce the cost of treatment for the patient or healthcare insurer. Using a randomised controlled trial, Ludewig & Borstad (2003) compared an 8-week standardised home-exercise program versus both symptomatic and asymptomatic control groups receiving no intervention. The home-exercise program involved a combination of stretches and strengthening exercises for peri-scapular muscles and muscles of the rotator cuff in the affected shoulder. The study used a 100-point shoulder rating questionnaire (SRQ), and the 10-question optional occupation setting section of the SPADI relating to work related pain and disability. Measurements were taken prior to the intervention phase and 10 weeks after the commencement of the intervention. After the intervention the SRQ for the intervention group had a statistically significant improvement over control participants ($p < 0.001$) with an increase of 12.1 ± 2.14 points and an effect size of $d = 5.67$ representing an 'extremely large' effect size (Hopkins, 2010).² Both the symptomatic and asymptomatic control groups demonstrated minimal change in SRQ score. Prior to intervention there was no significant difference between the intervention group and symptomatic control for measures of work related pain and disability. Following the intervention, however, there was significant difference between the two groups for both measurements ($p < 0.05$). In the intervention group work related pain reduced by an average of 2 ± 0.29 points and work related disability by an average of 1.6 ± 0.30 points, both representing an 'extremely large' effect size of $d = 5.4$ and $d = 7.0$ respectively. The success of the home-exercise program was unexpected as adherence to unsupervised exercise is often poor when compared to supervised exercise (Cox, Burke, Gorely, Beilin, & Puddey, 2003) and each participant received only 1-2 brief check-ups during the 8-week intervention phase. Participants recorded a daily exercise log however this data was not reported leaving actual adherence to the program unknown. Although improvements were gained with the home-exercise intervention, participants were

² Effect sizes reported in this section were not reported by Ludewig and Borstad (2003) in the text but were calculated by the author based on the results presented in the article.

required to complete a program lasting twice as long as the supervised exercise program used by Roy et al. (2009).

3.4 Home-Exercise vs Supervised Exercise

Ludewig & Borstad (2003) demonstrated the clinical benefit of an 8-week standardised home-exercise program in those suffering from shoulder impingement syndrome. Whether home-exercise provides similar benefits to supervised exercise is yet to be answered. Walther et al. (2004) sought to compare supervised and unsupervised exercise prescription using a prospective randomised trial involving three intervention groups over a 12-week period. The first group received a standardised home-exercise program, the second supervised exercise prescription, and the third received a functional shoulder brace to help control forces acting on the shoulder. Participants in the home-exercise group received four initial training sessions and were provided with a printed sheet with instructions on how to perform each exercise. Participants in the supervised exercise group received, on average, 30 sessions with the physiotherapist over the 12-week intervention. Adherence to the exercise program was assessed using an exercise diary, with the patients required to record when they performed the exercises. Walther et al. (2004) failed to report adherence data although they did state participants in the home-exercise group “fulfilled the guidelines concerning the frequency of their exercises” (p.419). The parameters within the guideline were not reported. The primary aim of both the home-exercise and supervised exercise program was based on the premise that strengthening muscles that depress the humeral head would centre the humeral head within the glenoid fossa and thus reduce impingement within the subacromial space. The primary outcome measure was the Constant-Murley score which contains measurements of pain, pain-free shoulder mobility, shoulder strength, and ability to perform activities of daily living. Both the supervised and home-exercise groups demonstrated improvements in pain, shoulder function and range of motion within the Constant-Murley score yet no statistically significant difference was found between the home-exercise and supervised exercise interventions ($p < 0.05$). The findings reported in this study demonstrate that a 12-week

prescribed home-exercise program, based on the premise that strengthening the muscles of the rotator cuff to centre the humeral head within the glenoid fossa, compares favourably with a supervised exercise program in reducing clinical measures of pain and disability in those with shoulder impingement. It is important to note that the home-exercise program achieved similar results to the supervised exercise program but with 26 fewer sessions with the physiotherapist. Although cost-effectiveness was not reported it is obvious that there may be fiscal benefits to a home-exercise approach.

4. Manual Therapy

The previous section of this literature review considered the reported effect of both supervised and home-exercise for the treatment of shoulder impingement. Supervised exercise was demonstrated to reduce variables of pain and disability, and improve levels of function and mobility within the shoulder complex, however generally did not improve strength variables measured. When studied alone home-exercise was demonstrated to improve the pain and disability in those with shoulder impingement, and was found to compare favourably with supervised exercise prescription. This review will now critically analyse studies relating to manual therapy and osteopathic treatment, a form of manual therapy, for those with shoulder impingement syndrome.

Manual therapy is a generic term used to describe the application of hands-on technique to joints and soft-tissues of the body. It is used in the treatment of shoulder impingement yet, unlike exercise prescription, there is relatively limited literature in regards to its effectiveness when treating shoulder impingement syndrome. Bergman et al. (2004) and Winters, Sobel, Groenier, Arendzen, & de Jong (1997) investigated the effect of manual therapy for generalised shoulder pain. This literature review is concerned with the treatment of shoulder impingement syndrome therefore the studies by Bergman et al. (2004) and Winters et al. (1997) will not be reviewed here. This section will critically analyse studies of manual therapy for the treatment of specifically shoulder impingement syndrome.

4.1 High-Velocity Low-Amplitude Thrust

Shoulder impingement syndrome has a complex aetiology with various factors implicated in its development (Michener et al., 2003). Altered posture of the thoracic and cervical spine contribute to the development of shoulder impingement both directly (Kebaetse, McClure, & Pratt, 1999) and indirectly by altering scapular posture (Ludewig & Cook, 2000). It is reasoned that improving function of the spinal segments related to scapular posture may help improve symptoms of shoulder impingement.

High-velocity low-amplitude (HVLA) thrust improves range of motion in spinal segments (Martinez-Segura, Fernandez-de-las-Penas, Ruiz-Saez, Lopez-Jimenez, Rodriguez-Blanci, 2006) and has recently been shown to improve active range of motion of the shoulder when applied to the spine (Strunce, Walker, Boyles, & Young, 2009). High-velocity low-amplitude thrust has also been employed to affect measures of pain and disability in those with shoulder impingement syndrome (Boyles et al., 2009). Boyles et al. investigated the short-term (48-hour) effect of HVLA in those with shoulder impingement. A single-system design was used, with 56 participants receiving HVLA thrusts to restricted segments found in the cervical and thoracic spine, and associated ribs. Pain and disability was measured using the SPADI and current pain intensity was measured using the numeric pain rating scale (NPRS) during provocative tests to the shoulder. Variables were measured prior to and 48 hours following the intervention. Following the intervention the group mean change for the SPADI was a 6.8% reduction with a 'small' effect size of $d=0.35$. The 6.8% reduction was less than that needed to reach the MCID for SPADI (Vaughan & DiVenuto, 2004). Reductions using the NPRS at the 48-hour follow-up session ranged from 0.63 to 1.2 points, with all measures reaching a statistically significant level of change ($p<0.05$). None, however, represented a MCID for the NPRS reported to be a 2-point shift by Farrar, Young, LaMoreaux, Werth, & Poole (2001). Manual therapy treatments commonly consist of the combination of multiple techniques and although the reductions in pain and disability did not reach the MCID for either the SPADI or NPRS, it must be remembered that the intervention involved only a single treatment intervention and therefor is not representative of typical clinical practice.

4.2 Trigger Points

Using a single-group research design, Hidalgo-Lozano, Fernandez-de-las-Penas, Diaz-Rodriguez, Gonzalez-Iglesias, Palacios-Cena, & Arroyo-Morales (2011) used manual therapy techniques applied to active trigger points within the supraspinatus, infraspinatus, subscapularis, levator scapulae, and pectoralis major muscles in people suffering from shoulder impingement. Each participant received 4 treatments over a 2-

week intervention period, with pain on arm elevation assessed pre- and post-treatment and at a 1-month follow-up using a 10cm VAS. Following the intervention, average pain for the group had reduced from mean 5.1 ± 1.9 cm to 1.3 ± 0.5 cm with a 'very large' effect size of $d=3.1$. The 3.8cm shift was of clinical importance as the MCID for VAS in those affected by rotator cuff pathology is reported to be 1.4cm (Tashjian, Deloach, Porucznik, & Powell, 2009). The results demonstrate the short-term benefit of manual techniques to trigger points within muscles of the shoulder girdle for pain intensity in those with shoulder impingement syndrome. When measurements were taken at the 1-month follow-up session the average pain score for the group had risen to 3.8 ± 1.3 cm. The pre-intervention to 1-month follow-up shift of 1.3cm still demonstrated a 'moderate' effect size of $d=0.8$ although fell below the MCID, raising questions about the long-term benefit of treatment of active trigger points. Systematic reviews of the literature have found little to no evidence for the long-term benefit of manual techniques to trigger points (Rickards, 2006; Vernon & Schneider, 2009), although it has been argued that long-term benefit can come only when all contributing factors to trigger point development are addressed (Huguenin, 2004). Although only short-term benefits have been demonstrated for both spinal manipulation (Boyles et al., 2009) and trigger point treatment (Hidalgo-Lozano et al., 2011), these techniques may be demonstrated to be more effective when incorporated into a more complete treatment regime, especially for short-term changes in pain experienced by those with shoulder impingement.

4.3 Osteopathic Treatment

Osteopathic treatment uses techniques closely associated to those employed by other forms of manual therapy, and has been shown to provide clinical improvements in conditions such as: lower back pain (Licciardone et al., 2005); and neck pain (Fryer et al., 2005). To date, there appears to be only one study (Musil, 2006) that aimed to measure the effect of manual osteopathic treatment for those with shoulder impingement syndrome. A practising osteopath carried out a two-group repeated measure study that sought to compare the effect of manual osteopathic treatment

with a standardised self-training exercise program (Musil, 2006). The osteopathic group received 6 osteopathic treatments over a 12-week period, while the self-training exercise group was given a standardised exercise routine with the aim of strengthening the rotator cuff and scapular stabilisers, and increasing flexibility of the shoulder girdle and related spinal segments. The exercises were completed over a 12-week period, with each participant receiving 3 supervised sessions within that time. The primary outcome measure was the Constant-Murley score. Both groups achieved improvement in overall Constant-Murley score although no differences were found between groups. No significant difference was found between groups for activities of daily living and shoulder strength. Unlike previous studies which have reported greater improvements in pain intensity when manual therapy and exercise prescription have been combined (Bang & Deyle, 2000; Conroy & Hayes, 1998), Musil (2006) reported no significant difference between groups for pain intensity. Differences were, however, found between groups in regards to pain-free mobility of the shoulder, with the osteopathic group achieving significantly greater gains over the exercise group, again a result that is different from other studies (Conroy & Hayes, 1998).

The study conducted by Musil (2006) had limitations in the reporting of methods and results which precluded interpretation of the findings and decreased the reproducibility of the study. The study failed to specify which osteopathic techniques were used and the areas of the body that were subject to treatment. Symptoms of impingement were said to be relieved by improving the mobility of the thoracic spine yet no mention was made as to how this was achieved. High-velocity low-amplitude to the thoracic spine has been shown to improve symptoms related to shoulder impingement (Boyles et al., 2009), yet other osteopathic techniques such as articulation and functional technique may be employed to improve thoracic spine mobility (Ward, 2003). Similarly vague descriptions were given for techniques used for balancing muscles of the shoulder region, treatment of the stomach, and treatment of the thoracic diaphragm (Musil, 2006). The reporting by the author leaves the

treatment approach for each of these descriptions unknown and no other study could be found relating to osteopathic treatment of shoulder impingement syndrome.

5. Exercise Prescription combined with Manual Therapy

The previous section of this literature review critically analysed studies relating to manual therapy and osteopathy for the treatment of shoulder impingement syndrome. Although there is only a small amount of current literature it seems the application of single manual therapy techniques provides small clinical improvements in measures of pain and disability, however there is a need for further evidence into the effect of a comprehensive manual therapy treatment. There is emerging evidence that manual therapy, when combined with exercise prescription provides greater clinical improvements over exercise alone (Kromer et al., 2009). This section of the literature review will critically analyse studies relating to manual therapy in combination with exercise for those with shoulder impingement syndrome.

5.1 Introduction of an Active and Passive Treatment Model

Exercise prescription and manual therapy form part of a non-operative treatment plan for shoulder impingement syndrome (Conroy & Hayes, 1998) and are associated with clinical improvements in pain and disability. Liebenson (1996) describes a theoretical model for the treatment of musculoskeletal disorders that combines both 'active' and 'passive' care for the management of subacute, recurrent, and chronic conditions. Liebenson argues that no single form of treatment can adequately address the multiple contributors to musculoskeletal conditions. Combining active exercises with passive manual therapy has become common practice when treating musculoskeletal conditions such as low back pain (van Middelkoop et al., 2011), neck pain (Miller et al., 2010), and whiplash (Bronfort, Evans, Nelson, Aker, Goldsmith, & Vernon, 2001), and there is emerging evidence that manual therapy used as an adjunct to exercise prescription provides superior benefits over exercise prescription used alone (Kromer et al., 2009).

5.2 Exercise Prescription combined with a Single Manual Technique

It has been reported that insufficient anterior-inferior length of the gleno-humeral capsule can be a primary cause of shoulder impingement syndrome (Hjelm et al., 1996; Lewis et al., 2001). Conroy & Hayes (1998) conducted a randomised controlled trial to investigate the additional effect of gleno-humeral and sub-acromial joint mobilisation when used in conjunction with a comprehensive treatment plan including exercise prescription. The study involved 14 participants randomised into a control group ($n=7$) receiving comprehensive treatment (hot packs, rotator cuff and peri-scapular muscle strengthening exercises, gleno-humeral stretching exercises, soft-tissue mobilisation, and activity advice), and an experimental group ($n=7$) receiving conservative treatment with additional mobilisation of the gleno-humeral and sub-acromial joints. The intervention was carried out over 3 weeks with participants in each group receiving 9 treatments. Clinical outcome measures were taken prior to the intervention and within 1 to 3 days following its completion. The outcome measures were: a 100mm VAS for 24-hour pain and pain experienced with the Neer impingement test; active pain-free range of motion of the shoulder; and functional ability of the shoulder during three functional shoulder tests. Following the intervention the authors reported no difference between groups for both pain-free active range of motion of the shoulder and the three functional shoulder tests, although both groups achieved significant improvement in both variables. For 24-hour pain, the control group had a pain reduction of 2mm ($d=0.08$) following the intervention while the experimental group had a pain reduction of 37mm representing a 'large' effect size of $d=1.7$ (Hopkins, 2010). The experimental group demonstrated improvements in pain intensity during the Neer test with a reduction of 28mm and a 'large' effect size of $d=1.2$, whilst the control group demonstrated 'trivial' change (reduction = 3mm - $d=0.1$). The reductions achieved in the experimental group for 24-hour pain and pain with the Neer test was well above the MCID for VAS (Tashjian et al., 2009). The results demonstrated by the control group suggest that exercise prescription as part of a comprehensive treatment plan is not associated with clinical improvements in pain. This finding is inconsistent with other studies which have shown exercise prescription reduces pain intensity in

those with shoulder impingement syndrome (Lombardi et al., 2008; Ludewig & Borstad, 2003; Morrison et al., 1997; Roy et al., 2009; Walther et al., 2004). The study by Conroy & Hayes (1998) was, however, inadequately powered with a small sample size ($n=7$) and an observed power of 0.75 therefore the likelihood of a Type II error occurring cannot be ruled out.

The results reported by Conroy & Hayes (1998) suggest that mobilisation techniques to the gleno-humeral and sub-acromial joints, used in conjunction with exercise prescription, provides greater reductions in pain levels over those treated with exercise alone. This finding was further demonstrated in a study by Kachingwe et al. (2008) who, using a randomised controlled trial, reported that participants receiving gleno-humeral mobilisation in addition to a supervised exercise program aimed at strengthening the rotator cuff and peri-scapular musculature gained greater reductions in pain than those receiving supervised exercise alone. Participants ($n=33$) received 6 treatments over 6 weeks and were randomised into four groups: 1) a control group receiving physician advice; 2) a supervised exercise group; and two groups performing the supervised exercise program with the addition of either a 3) passive or 4) active mobilisation technique to the gleno-humeral joint. Clinical outcome measures included: VAS for 24-hour pain, and on the Neer and Hawkins tests; active range of motion of the shoulder in flexion and scaption; and pain and disability using the SPADI. Following the intervention participants in all groups achieved significant reductions in pain, improvement in function, and increased active range of motion. The authors reported that there was no significant difference found between groups for each of the variables. Although no difference was found between groups the results did, however, suggest that participants in both the active and passive mobilisation groups achieved greater reductions in pain scores over participants in either the control or supervised exercise groups. Mean percentage reductions for the passive mobilisation group ranged from $44 \pm 39\%$ to $58 \pm 39\%$, whilst reductions in the supervised exercise group ranged from $21 \pm 112\%$ to $44 \pm 57\%$. The general findings reported by Kachingwe et al. (2008) are in accord with those found by Conroy & Hayes

(1998) in suggesting that mobilisation of the gleno-humeral joint provides additional reductions in pain intensity when combined with exercise prescription for those with shoulder impingement syndrome over exercise prescription alone.

5.3 Exercise Prescription combined with a Comprehensive Manual Therapy Treatment

Both Conroy & Hayes (1998) and Kachingwe et al. (2008) demonstrated that the addition of a single manual technique to an exercise program provides greater reductions in pain intensity than exercise alone for those with shoulder impingement syndrome. Manual therapy does, however, typically consist of a combination of techniques rather than one alone. Tate, McClure, Young, Salvatori, & Michener (2010) conducted a case series that investigated the effect of exercise prescription when combined with a comprehensive manual therapy intervention over a 6 to 8 week period. Ten participants completed an exercise program consisting of strengthening exercise for the rotator cuff and scapular stabilisers, as well as shoulder flexibility exercises. Participants also received 10 manual therapy treatments that addressed dysfunction in the thoracic spine, posterior shoulder, and gleno-humeral joint capsule. Techniques included mobilisation, HVLA thrust, and manual stretching. Clinical outcome measures were; pain intensity using the NPRS when at rest, during normal activities, and during strenuous activities; shoulder function using the DASH; and patients perceived level of change using the global rating of change (GRC). Measures were taken fortnightly from initial assessment up to 12 weeks. Participants were said to have a successful outcome if they reported a 'moderately better' score on the GRC and a 50% improvement in the DASH score. Using the above criteria, the authors reported a successful outcome for 6/10 participants at 6 weeks, and 8/10 participants at 12 weeks. From 0 to 12 weeks the group mean for the DASH score improved by 22.1 ± 10.9 points with a 'very large' effect size of $d=2.0$. The group mean for the combined pain intensity score, scored out of 30 points, reduced by 5.9 ± 6.2 points with a 'moderate' effect size of $d=0.95$. Case series typically begin with a sequence of baseline measurements to establish symptom stability, with five measurements recommended

to ensure the underlying stability of the measurements (Logan, Hickman, Harris, & Heriza, 2008). The authors did, however, fail to take baseline measurements which could weaken the extent to which post-treatment change might be attributed to the intervention. Causal relationships cannot be definitively ascertained from case series (Backman, Harris, Chisholm, & Monette, 1997), however if the pre-treatment baseline is prolonged and stable some authors claim that inferences can be made about cause and effect (Sim, 1995). In the case of Tate et al. (2010) it is unknown whether the reduction in pain and improved functional ability of participants was directly related to the intervention, or whether it was another factor such as natural resolution of the condition. The results do, however, suggest a temporal relationship between the application of manual therapy and clinically beneficial improvements in measures of pain and function in those with shoulder impingement syndrome.

5.4 Exercise Prescription with and without Manual Therapy

Clinically beneficial results following exercise prescription combined with manual therapy has been demonstrated in those with shoulder impingement (Tate et al., 2010). The addition of a single manual technique to exercise prescription has also been shown to achieve more beneficial results over exercise alone (Conroy & Hayes, 1998; Kachingwe et al., 2008). Using a prospective randomised clinical trial Bang & Deyle (2000) demonstrated that participants receiving supervised exercise combined with a comprehensive manual therapy treatment gained superior clinical benefits over those receiving supervised exercise alone. The exercise intervention employed strengthening exercises for the rotator cuff and scapular stabilisers. All participants ($n=50$), randomised to an exercise or manual therapy group, completed the exercise program which consisted of 6 supervised training sessions and at home-exercises over 6 weeks. The manual therapy group received additional manual therapy at each session. Manual therapy included joint mobilisation of the shoulder girdle, the cervical and thoracic spine, and soft-tissue technique to peri-scapular muscles. Following the intervention both groups had improvements in measures of pain intensity, function, and shoulder strength, however those receiving manual therapy were shown to have greater

improvements over those receiving exercise alone. As in previous studies (Conroy & Hayes, 1998; Kachingwe et al., 2008) those receiving a combination of manual therapy and exercise had greater reductions in pain intensity over those receiving exercise alone. The manual therapy group had a 70% ($d=2.0$) reduction in pain intensity, while the exercise group experienced a reduction of 35% ($d=0.8$). Bang & Deyle (2000) measured shoulder function using a functional assessment questionnaire based on the Oswestry lower back pain questionnaire. Shoulder function in the manual therapy group increased by 35% ($d=2.1$), and 17% ($d=0.7$) in the exercise group, demonstrating that those receiving additional manual therapy achieved greater improvement over those receiving exercise alone. The results for shoulder function were in contrast to those reported by Kachingwe et al. (2008) who found no significant difference between similar groups. For strength, the exercise group had a 'trivial' increase of 6% ($d=0.16$) which is consistent with other studies which have reported small improvements in strength following exercise prescription (Haahr et al., 2005; Lombardi et al., 2008; Roy et al., 2009). Similarly, those receiving manual therapy were found to have a 'small' increase in strength of 16% ($d=0.41$) post-intervention. The authors speculate that this was due to stimulation of joint mechanoreceptors and subsequent pain inhibition following manual therapy. Further to this, Bialosky, Bishop, Price, Robinson, & George (2009) propose a model for the mechanisms of pain inhibition that is observed following manual therapy. The authors suggest manual therapy reduces local inflammatory mediators and down-modulates nociceptive signals in the central nervous system, and thereby reduces the perception of pain in individuals. Henriksen, Rosager, Aaboe, Graven-Nielsen, & Bliddal (2011) found experimental knee pain reduced knee flexion and extension strength by 5 to 15% and suggested that increased pain intensity impairs muscle strength.

5.5 Summary of Exercise Prescription combined with Manual Therapy

The results reported by Bang & Deyle (2000) demonstrate that manual therapy combined with exercise prescription provides increased function and strength, and decreased pain intensity over exercise alone following a 6-week intervention.

Following a 12-week intervention Senbursa, Baltaci, & Atay (2011) reported that a combined treatment approach, including manual therapy and strengthening exercises to the shoulder girdle, achieved faster reductions in pain over exercise alone. The authors did, however, report no significant difference ($p>0.05$) between groups at the conclusion of the intervention. This suggests that the combined treatment approach provides a more efficient and cost-effective option over exercise alone. It does however raise the question of the long-term benefit of manual therapy plus exercise over exercise alone.

6. Conclusion

Many non-operative treatments have been shown to be effective in the treatment of shoulder impingement syndrome, yet little is known about the effectiveness of manual osteopathic treatment for the condition. Supervised and home-exercises, when studied alone or with the addition of manual therapy, have been demonstrated to improve measurements of pain, function, disability, mobility, and quality of life in people with shoulder impingement syndrome. To date only one study has measured the effect of manual osteopathic treatment for those with shoulder impingement however the study contained limitations in reporting of methods and results which preclude interpretation of findings. The use of a semi-standardised osteopathic treatment protocol has previously been employed for studies involving musculoskeletal disorders such as lower back and neck pain yet no study has reported the use of a semi-standardised osteopathic treatment protocol for the treatment of shoulder impingement syndrome.

Therefore the aim of the study reported in section 3 of this thesis is: To investigate the effect of a home-exercise program with and without the addition of a semi-standardised osteopathic treatment protocol in people with shoulder impingement syndrome

7. References

The Accident Compensation Corporation (2004). *The diagnosis and management of soft tissue shoulder injuries and related disorders, 2004.*

Retrieved September 27, 2009, from <http://www.acc.co.nz/providers/clinical-best-practice/acc-review/index.htm>

Andersen, N.H., Sojbjerg, J.O., Johannsen, H.V., & Sneppen, O. (1999). Self-training versus physiotherapist-supervised rehabilitation of the shoulder in patients treated with arthroscopic subacromial decompression: a clinical randomized study. *The Journal of Shoulder and Elbow Surgery, 8*(2), 99-101.

Backman, C.L., Harris, S.R., Chisholm, J.A., & Monette, A.D. (1997). Single-subject research in rehabilitation: a review of studies using AB, withdrawal, multiple baseline, and alternating treatments designs. *Archives of Physical Medicine and Rehabilitation, 78*(10), 1145-1153.

Bang, M.D., & Deyle, G.D. (2000). Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. *Journal of Orthopaedic and Sports Physical Therapy, 30*(3), 126-137.

Bergman, G.J., Winters, J.C., Groenier, K.H., Pool, J.J., Meyboom-de Jong, B., Postema, K., & van der Heijden, G.J. (2004). Manipulative therapy in addition to usual medical care for patients with shoulder dysfunction and pain. *Annals of Internal Medicine, 141*(6), 432-439.

Bialosky, J.E., Bishop, M.D., Price, D.D., Robinson, M.E., & George, S.Z. (2009). The mechanisms of manual therapy in the treatment of musculoskeletal pain: a comprehensive model. *Manual Therapy, 14*(5), 531-538.

- Bigliani, L.U., Ticker, J.B., Flatow, E.L., Soslowky, L.J., & Mow, V.C. (1991). The relationship of acromial architecture to rotator cuff disease. *Clinic in Sports Medicine, 10*(4), 823-838.
- Bot, S.D.M., van der Waal, J.M., Terwee, C.B., van der Windt, D.A.W.M., Schellevis, F.G., Bouter, L.M., & Dekker, J. (2005). Incidence and prevalence of complaints of the neck and upper extremity in general practice. *Annals of the Rheumatic Diseases, 64*(1), 118-123.
- Boyles, R.E., Ritland, B.M., Miracle, B.M., Barclay, D.M., Faul, M.S., Moore, J.H., Koppenhaver, S.L., & Wainner, R.S. (2009). The short-term effects of thoracic spine thrust manipulation on patients with shoulder impingement syndrome. *Manual Therapy, 14*(4), 375-380.
- Bronfort, G., Evans, R., Nelson, B., Aker, P.D., Goldsmith, C.H., & Vernon, H. (2001). A randomized clinical trial of exercise and spinal manipulation for patients with chronic neck pain. *Spine, 26*(7), 788-797.
- Brox, J.I., Gjengedal, E., Uppheim, G., Bohmer, A.S., Brevik, J.I., Ljunggren, A.E., & Staff, P.H. (1999). Arthroscopic surgery versus supervised exercises in patients with rotator cuff disease (stage II impingement syndrome): a prospective, randomized, controlled study in 125 patients with a 2 and a half year follow-up. *The Journal of Shoulder and Elbow Surgery, 8*(2), 102-111.
- Brukner, P., & Khan, K. (2009). *Clinical sports medicine*. North Ryde, New South Wales, Australia: McGraw-Hill Australia Pty Ltd.
- Calis, M., Akgun, K., Birtane, M., Karacan, I., Calis, H., & Tuzun, F. (2000). Diagnostic values of clinical diagnostic tests in subacromial impingement syndrome. *Annals of the Rheumatic Disease, 59*(1), 44-47.

- Chipchase, L.S., O'Connor, D.A., Costi, J.J., & Krishnan, J. (2000). Shoulder impingement syndrome: Preoperative health status. *Journal of Shoulder and Elbow Surgery*, 9(1), 12-15.
- Cloke, D.J., Lynn, S.E., Watson, H., Purdy, S., Steen, I.N., & Williams, J.R., (2008). A pilot randomized, controlled trial of treatment for painful arc of the shoulder. *The Journal of Shoulder and Elbow Surgery*, 17(1), S17-S21.
- Conroy, D.E., & Hayes, K.W. (1998). The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. *Journal of Orthopaedic and Sports Physical Therapy*, 28(1), 3-14.
- Cox, K.L., Burke, V., Gorely, T.J., Beilin, L.J., & Puddey, I.B. (2003). Controlled Comparison of Retention and Adherence in Home- vs Center-Initiated Exercise Interventions in Women Ages 40–65 Years: The S.W.E.A.T. Study (Sedentary Women Exercise Adherence Trial). *Preventive Medicine*, 36(1), 17-29.
- Cummins, C.A., Sasso, L.M., & Nicholson, D. (2009). Impingement syndrome: temporal outcomes of non-operative treatment. *Journal of Shoulder and Elbow Surgery*, 18(2), 172-177.
- Dickens, V.A., Williams, J.L., & Bharna, M.S. (2005). Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. *Physiotherapy*, 91(3), 159-164.
- Diederichsen, L.P., Norregaard, J., Dyhre-Poulsen, P., Winther, A., Tufekovic, G., Bandholm, T., Rasmussen, L.R., & Krogsgaard, M. (2009). The activity pattern of shoulder muscles in subjects with and without subacromial impingement. *Journal of Electromyography and Kinesiology*, 19(5), 789-799.

- Dinnes, J., Loveman, E., McIntyre, L., & Waugh, N. (2003). The effectiveness of diagnostic tests for the assessment of shoulder pain due to soft tissue disorders: a systematic review. *Health Technology Assessment, 7*(29). Retrieved October 12, 2011, from <http://www.hta.ac.uk/execsumm/summ729.htm>
- Erol, O., Ozcakar, L., & Celiker, R. (2008). Shoulder rotator strength in patients with stage I-II subacromial impingement: relationship to pain, disability, and quality of life. *Journal of Shoulder and Elbow Surgery, 17*(6), 893-897.
- Farrar, J.T., Young, J.P., Jr., LaMoreaux, L., Werth, J.L., & Poole, R.M. (2001). Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain, 94*(2), 149-158.
- Fryer, G., Alvizatos, J., & Lamaro, J. (2005). The effect of osteopathic treatment on people with chronic and sub-chronic neck pain: A pilot study. *International Journal of Osteopathic Medicine, 8*(2), 41-48.
- Gebremariam, L., Hay, E.M., Koes, B.W., & Huisstede, B.M. (2011) Effectiveness of surgical and postsurgical interventions for the subacromial impingement syndrome: a systematic review. *Archives of Physical Medicine and Rehabilitation, 92*(11), 1900-1913.
- Grant, H.J., Arthur, A., & Pichora., D.R. (2004). Evaluation of interventions for rotator cuff pathology: a systemic review. *Journal of Hand Therapy, 17*(2), 274-299.
- Guerra de Hoyos, J.A., Andrés Martín Mdel, C., Bassas y Baena de Leon, E., Vigára Lopez, M., Molina López, T., Verdugo Morilla, F.A., González Moreno, M.J. (2004). Randomised trial of long term effect of acupuncture for shoulder pain. *Pain, 112*(3), 289-298.

Haahr, J.P., Ostergaard, S., Dalsgaard, J., Norup, K., Frost, P., Lausen, S., Holm, E.A., & Andersen, J.H. (2005). Exercises versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up. *Annals of the Rheumatic Diseases*, 64(5), 760-764.

Henriksen, M., Rosager, S., Aaboe, J., Graven-Nielsen, T., & Bliddal, H. (2011). Experimental knee pain reduces muscle strength. *The Journal of Pain*, 12(4), 460-467.

Hidalgo-Lozano, A., Fernandez-de-las-Penas, C., Diaz-Rodriguez, L., Gonzalez-Iglesias, J., Palacios-Cena, D., & Arroyo-Morales, M. (2011). Changes in pain and pressure pain sensitivity after manual treatment of active trigger points in patients with unilateral shoulder impingement: a case series. *Journal of Bodywork and Movement Therapies*, 15(4), 399-404.

Hjelm, R., Draper, C., & Spencer, S. (1996). Anterior-inferior capsular length insufficiency in the painful shoulder. *The Journal of Orthopaedic & Sports Physical Therapy*, 23(3), 216-222.

Hopkins, W.G., (2010). Lineal models and effect magnitudes for research, clinical and practical applications. *Sports Science*, 14, 49-57.

Huguenin, L.K. (2004). Myofascial trigger points: the current evidence. *Physical Therapy*, 5(1), 2-12.

Husby, T., Haugstvedt, J.R., Brandt, M., Holm, I., & Steen, H. (2003). Open versus arthroscopic subacromial decompression: a prospective, randomized study of 34 patients followed for 8 years. *Acta Orthopaedica Scandinavia*, 74(4), 408-414.

Johansson, K., & Ivarson, S. (2009). Intra- and interexaminer reliability of four manual shoulder maneuvers used to identify subacromial pain. *Manual Therapy, 14*(2), 231-239.

Kachingwe, A.F., Phillips, B., Sletten, E., & Plunkett, S.W. (2008). Comparison of manual therapy techniques with therapeutic exercise in the treatment of shoulder impingement: a randomized controlled pilot clinical trial. *The Journal of Manual and Manipulative Therapy, 16*(4), 238-247.

Karthikeyan, S., Kwong, H.T., Upadhyay, P.K., Parsons, N., Drew, S.J., & Griffin, D. (2010). A double-blind randomised controlled study comparing subacromial injection of tenoxicam or methylprednisolone in patients with subacromial impingement. *The Journal of Bone and Joint Surgery, 92*(1), 77-82.

Kebaetse, M., McClure, P., & Pratt, N.A. (1999). Thoracic position effect on shoulder range of motion, strength, and three-dimensional scapular kinematics. *Archives of Physical Medicine and Rehabilitation, 80*(8), 945-950.

Koester, M.C., George, M.S., & Kuhn, J.E. (2005). Shoulder impingement syndrome. *The American Journal of Medicine, 118*(5), 452-455.

Kromer, T.O., Tautenhahn, U.G., de Bie, R.A., Staal, J.B., & Bastiaenen, C.H.G. (2009). Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. *Journal of Rehabilitation Medicine, 41*(11), 870-880.

Leroux, J.L., Codine, P., Thomas, E., Pocholle, M., Mailhe, D., & Blotman, F. (1994). Isokinetic evaluation of rotational strength in normal shoulders and shoulders with impingement syndrome. *The Journal of Shoulder and Elbow Surgery, 4*(1), S23.

- Lewis, J.S., Green, A., & Dekel, S. (2001). The aetiology of subacromial impingement syndrome. *Physiotherapy*, 87(9), 458-469.
- Lewis, J.S., Wright, C., & Green, A. (2005). Subacromial impingement syndrome: the effect of changing posture on shoulder range of movement. *Journal of Orthopaedic and Sports Physical Therapy*, 35(2), 72-87.
- Licciardone, J.C., Brimhall, A.K., & King, L.N. (2005). Osteopathic manipulative treatment for low back pain: a systematic review and meta-analysis of randomized controlled trials. *BMC Musculoskeletal Disorders*, 4(6). Retrieved June 11, 2011, from <http://www.biomedcentral.com/content/pdf/1471-2474-6-43.pdf>.
- Liebenson C., (1996). *Rehabilitation of the spine: a practitioner's manual*. Baltimore, Maryland, United States of America: Lippincott Williams & Wilkins.
- Logan, L.R., Hickman, R.R., Harris, S.R., & Heriza, C.B. (2008). Single-subject research design: recommendations for levels of evidence and quality rating. *Developmental Medicine and Child Neurology*, 50(2), 99-103.
- Lombardi, I., Jr, Magri, A.G., Fleury, A.M., da Silva, A.C., & Natour, J. (2008). Progressive resistance training in patients with shoulder impingement syndrome: a randomized controlled trial. *Journal of Arthritis and Rheumatism*, 59(5), 615-622.
- Ludewig, P.M., & Borstad, J.D. (2003). Effects of a home exercise programme on shoulder pain and functional status in construction workers. *Occupation and Environmental Medicine*, 60(11), 841-849.

- Ludewig, P.M., & Cook, T.M. (2000). Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. *Physical Therapy, 80*(3), 276-291.
- Luime, J.J., Koes, B.W., Hendriksen, I.J., Burdorf, A., Verhagen, A.F., Miedema, H.S., & Verhaar, J.A. (2004). Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scandinavian Journal of Rheumatology, 33*(2), 73-81.
- MacGillivray, J.D., Fealy, S., Potter, H.G., & O'Brien, S.J. (1998). Multiplanar analysis of acromion morphology. *The American Journal of Sports Medicine, 26*(6), 836-840.
- Martinez-Segura, R., Fernandez-de-las-Penas, C., Ruiz-Saez, M., Lopez-Jimenez, C., Rodriguez-Blanci, C. (2006). Immediate effects on neck pain and active range of motion after a single cervical high-velocity low-amplitude manipulation in subjects presenting with mechanical neck pain: a randomized controlled trial. *The Journal of Manual and Manipulative Therapy, 29*(7), 511-517.
- McIlwraith, B. (2003). A survey of 1200 osteopathic patients in the United Kingdom. *Journal of Osteopathic Medicine, 6*(1), 7-12.
- Michener, L.A., McClure, P.W., & Karduna, A.R. (2003). Anatomical and biomechanical mechanisms of subacromial impingement syndrome. *Clinical Biomechanics, 18*(5), 369-379.
- van Middelkoop, M., Rubinstein, S.M., Kuijpers, T., Verhagen, A.P., Ostelo, R., Koes, B.W., & van Tulder, M.W. (2011). A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *European Spine Journal, 20*(1), 19-39.

- Miller, J., Gross, A., D'Sylva, J., Burnie, S.J., Goldsmith, C.H., Graham, N., Haines, T., Bronfort, G., & Hoving, J.L. (2010). Manual therapy and exercise for neck pain: A systematic review. *Manual Therapy, 15*(4), 334-354.
- Moraes, G.F.S., Faria, C.D.C.M., & Teixeira-Salmela, L.F. (2008). Scapular muscle recruitment patterns and isokinetic strength ratios of the shoulder rotator muscles in individuals with and without impingement syndrome. *Journal of Shoulder and Elbow Surgery, 17*(1), 48S-53S.
- Morl, F., Matkey, A., Bretschneider, S., Bernsdorf, A., & Bradl, I. (2010). Pain relief due to physiotherapy doesn't change the motor function of the shoulder. *Journal of Bodywork and Movement Therapies, 15*(3), 309-318.
- Morrison, D.S., Frogameni, A.D., & Woodworth, P. (1997). Non-operative treatment of subacromial impingement syndrome. *The Journal of Bone & Joint Surgery, 79*(5), 732-737.
- Mulyadi, E., Harish, S., O'Neil, J., & Rebello, R. (2009). MRI of impingement syndromes of the shoulder. *Clinical Radiology, 64*(3), 307-318.
- Musil, K., (2006). The treatment of the subacromial syndrome of the shoulder either by osteopathic treatment or by guided self-training. Retrieved September 15, 2009, from www.osteopathicresearch.com/paper_pdf/Anderl_engl.pdf
- Myers, J.B., Hwang, J., Pasquale, M.R., Blackburn, J.T., & Lephart, S.M. (2009). Rotator cuff coactivation ratios in participants with subacromial impingement syndrome. *Journal of Science and Medicine in Sport, 12*(6), 603-608.

- Park, H.B., Yokata, A., Gill, H.S., El Rassi, G., McFarland, E.G. (2005). Diagnostic accuracy of clinical tests for the different degrees of subacromial impingement syndrome. *The Journal of Bone and Joint Surgery*, 87(7), 1446-1455.
- Pribicevic, M., Pollard, H., & Bonello, R. (2009). An epidemiologic survey of shoulder pain in chiropractic practice in Australia. *Journal of Manipulative Physiological Therapeutics*, 32(2), 107-117.
- Rickards, L.D. (2006). The effectiveness of non-invasive treatments for active myofascial trigger point pain: a systematic review of the literature. *International Journal of Osteopathic Medicine*, 9(4), 120-136.
- Roy, J.S., Moffet, H., Hebert, L.J., & Lirette, R. (2009). Effect of motor control and strengthening exercises on shoulder function in persons with impingement syndrome: A single-subject study design. *Manual Therapy*, 14(2), 180-188.
- Santamato, V., Solfrizzi, V., Panza, F., Tondi, G., Frisardi, V., Leggin, B.G., Ranieri, M., & Fiore, P. (2009). Short-term effects of high-intensity laser therapy versus ultrasound therapy in the treatment of people with subacromial impingement syndrome: a randomized clinical trial. *Physical Therapy*, 89(7), 643-652.
- Seitz, A.L., & Michener, L.A. (2011). Ultrasonographic measures of subacromial space in patients with rotator cuff disease: a systematic review. *Journal of Clinical Ultrasound*, 39(3), 146-154.
- Senbursa, G., Baltaci, G., & Atay, A. (2011). The effectiveness of manual therapy in supraspinatus tendinopathy. *Acta Orthopaedica et Traumatologica Turcica*, 45(3), 162-167.

- Sim, J. (1995). The external validity of group comparative and single system studies. *Physiotherapy, 81*(5), 263-270.
- Spangehl, M.J., Hawkins, R.H., McCormack, R.G., & Loomer, R.L. (2002). Arthroscopic versus open acromioplasty: a prospective, randomized, blinded study. *Journal of Shoulder and Elbow Surgery, 11*(2), 101-107.
- Strunce, J.B., Walker, M.J., Boyles, R.E., & Young, B.A. (2009). The immediate effects of thoracic spine and rib manipulation on subjects with primary complaints of shoulder pain. *The Journal of Manual and Manipulative Therapy, 17*(4), 230-236.
- Tashjian, R.Z., Deloach, J., Porucznik, C.A., & Powell, A.P. (2009). Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease. *Journal of Shoulder and Elbow Surgery, 18*(6), 927-932.
- Tate, A.R., McClure, P.W., Young, I.A., Salvatori, R., & Michener, L.A. (2010). Comprehensive impairment-based exercise and manual therapy intervention for patients with subacromial impingement syndrome: a case series. *The Journal of Orthopaedic and Sports Physical Therapy, 40*(8), 474-493.
- Tucker, S., Taylor, N.F., & Green, R.A. (2011). Anatomical validity of the Hawkins-Kennedy test – a pilot study. *Manual Therapy, 16*(4), 399-402.
- Valadie III, A.L., Jobe, C.M., Pink, M.M., Ekman, E.F., & Jobe, F.W. (2000). Anatomy of provocative tests for impingement syndrome of the shoulder. *Journal of Shoulder and Elbow Surgery, 9*(1), 36-46.

- Vaughan, B., & DiVenuto, G. (2004). An introduction to the use of outcomes questionnaires in osteopathic practice. *Journal of Osteopathic Medicine*, 7(2), 85-95.
- Vernon, H., & Schneider, M. (2009). Chiropractic management of myofascial trigger points and myofascial pain syndrome: a systematic review of the literature. *Journal of Manipulation and Physiological Therapeutics*, 32(1), 14-24.
- Walther, M., Werner, A., Stahlschmidt, T., Woelfel, R., & Gohlke, F., (2004). The subacromial impingement syndrome of the shoulder treated by conventional physiotherapy, self-training, and a shoulder brace: Results of a prospective, randomized study. *Journal of Shoulder and Elbow Surgery*, 13(4), 17-23.
- Ward, R.C., (2003). *Foundation for osteopathic medicine*. Philadelphia, Pennsylvania, United States of America: Lippincott Williams & Wilkins.
- van der Windt, D.A., Koes, B.W., de Jong, B.A., & Bouter, L.M. (1995). Shoulder disorders in general practice: incidence, patient characteristics, and management. *The British Journal of General Practice*, 46(410): 519-523
- van der Windt, D.A., Koes, B.W., Deville, W., Boeke, A.J.P., de Jong, B.A., & Bouter, L.M. (1998). Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial. *British Medical Journal*, 317(7168), 1292-1296.
- Winters, J.C., Sobel, J.S., Groenier, K.H., Arendzen, H.J., & de Jong, B.M. (1997). Comparison of physiotherapy, manipulation, and corticosteroid injection for treating shoulder complaints in general practice: randomised, single blind study. *British Medical Journal*, 314(7090), 1320-1325.

Section 2: Report of Recruitment

Introduction to Report of Recruitment

During the course of this project difficulties were faced during the recruitment process. Due to the slow rate of recruitment and enrolment of participants, changes were made to both the original design of the study and the way in which the data was analysed and reported.

This interim chapter is arranged in four parts. Part 1 will outline the original research design proposed for this study and discuss the design options considered for the project. Part 2 reports the recruitment methods employed during the recruitment process while Part 3 reports the results of each recruitment strategy. Part 4 is a discussion on how the slow recruitment rate encountered during the recruitment process led to changes in the design and reporting of methods and results in the study.

1. Methodological Considerations – Research Design

This part provides a background to the research design considered for this study. Following is a brief discussion comparing the rigor of randomised controlled trials (RCT) in comparison to case series designs.

1.1 Comparison of Randomised Controlled Trial and Single System Research Design

The original aim of this study was to:

- a) measure the effect of a home-exercise program on variables of pain and disability experienced by participants suffering from shoulder impingement syndrome;
- b) compare these results with those observed in participants receiving the home-exercise program with the addition of osteopathic treatment

1.1.1 Randomised Controlled Trial

To achieve the aims of the study a comparative RCT was proposed consisting of two groups of participants (osteopathic and home-exercise). An RCT design is used when researchers wish to evaluate the effect of an intervention (eg. osteopathic treatment) on a designated variable within a population group, and to compare this effect against the same variable within a group receiving no intervention or a different intervention (Saks & Allsop, 2007). Data are reported in relation to group means, although some authors claim this method of data reporting leads to individual responses being lost (Sanders, 2003). An RCT design had been proposed as a number of weaker study designs had already documented the clinical benefit of manual therapy for the treatment of shoulder impingement syndrome (Boyles et al., 2009; Roy, Moffet, Hebert, & Lirette, 2009).

1.1.2 Case Series

The 'single system research design' (SSRD) is a descriptor that is sometimes used interchangeably with the term 'prospective case series'. An SSRD follows a single person (or 'system') over a time course, with the person acting as their own control (Domholdt, 2005). This design has been identified as being particularly suitable for osteopathic research as it is both cost-effective and accessible, and seeks to document and assess individual responses to an intervention (Sanders, 2003). This is in contrast to group research designs, such as RCTs, which compare between-group responses to interventions, which some believe leads to the possibility of beneficial or harmful individual responses being lost in the pooled data (Domholdt, 2005).

The A-B single-system design is a fundamental form of SSRD. It comprises measurements of a dependent variable through a baseline phase and a treatment phase. The baseline phase is conducted before any intervention is implemented, with the measurements used to establish any natural fluctuation in the patients presenting symptoms (Domholdt, 2005). Measurements are continued into the intervention

phase so as to monitor any response to treatment. Measurements in the treatment phase are then compared to the measurements taken in the baseline phase in order to establish any treatment effect. Some SSRD designs continue measurements into a post-intervention phase so as to monitor any sustained intervention effect.

1.2 Limitations of the SSRD

Limitations of the SSRD include threats to external and internal validity, ethical issues, and the relative infancy of the single-system design methodology (Domholdt, 2005). The SSRD is considered quasi-experimental as its main characteristic is that it manipulates a predictor variable (Sim, 1995). Research designs that are considered stronger, such RCTs, compare the results of the intervention group against a control group so that changes in the intervention can be attributed to the intervention. The lack of a control group is thought to decrease the strength of the outcomes measured in the SSRD. Domholdt (2005) describes the possibility of extraneous factors, such as natural maturation of disease having an effect on the outcome measures, therefore negatively affecting the internal validity of single-system studies. However, establishing a stable baseline is considered to allow the individual to act as their own control and therefore allow any change in outcome measurement from baseline to treatment phase to be attributed to the intervention (Sim, 1995).

2. Recruitment Methods

The primary difficulty faced during this project was that of participant recruitment. The original estimated number of participants required for the study was calculated using a statistical calculator (G*Power v3.1) (Faul, Erdfelder, Buchner, & Lang, 2009). Following the analysis of previous studies involving manual therapy and exercise prescription (Bang & Deyle, 2000; Conroy & Hayes, 1998; Boyles et al., 2009) the effect size expected in this study was estimated at $d=1$. Based on the estimated effect size of $d=1$ and a desired power of ≥ 0.8 , an *a priori* sample size was calculated at 2 groups of 17. Therefore 17 participants were required in both the osteopathic and home-exercise cohorts, with an estimated total of 34 participants. Allowing for dropouts it was intended that under ideal circumstances a total of 40 participants would be enrolled.

Marketing strategies employed in the recruitment process included the use of: posters and flyers; online advertising; and an editorial. The recruitment phase commenced in August of 2010 and continued for 12 months concluding in September 2011.

2.1 Posters and Flyers

Posters and flyers (Appendix A) were used throughout the duration of the recruitment phase. The site of each poster was regularly inspected and maintained for various durations of time (duration indicated in brackets below). The target populations and locations used are listed below.

2.1.1 General Population

Posters were positioned on publically accessible notice boards in various locations around central Auckland that were thought to have a high level of foot traffic. The locations used were:

In West Lynn and surrounding areas posters were placed in a:

- bakery (12 months);

- general health foods store (6 months);
- medical centre (10 months);
- Buddhist centre and function hall (2 months);
- a cafe in Kingsland (6 months)

2.1.2 Tertiary Institutions

Posters were placed at two tertiary institutions, with the primary target population being tertiary students. They were Unitec New Zealand and Wellpark College.

At Unitec New Zealand posters were positioned in:

- Clinic 41 Student Health and Osteopathic Clinic, in the waiting room and each private clinic room (12 months);
- numerous notice boards around the Carrington and Waitakere campuses (6 months).

At Wellpark College a poster was placed in the student common room for a period of 6 months.

2.1.3 At-risk Population

Shoulder impingement syndrome has a high incidence rate in those that work in a prolonged twisted and/or poor posture and in those who conduct a lot of work with their hands elevated above the shoulder level (Magnusson & Pope, 1998). The at-risk population was identified as those who undertake repetitive activities over shoulder height during work or recreation (Leclerc, Niedhammer, Landre, & Roquelaure, 2004). The population group targeted were: trade painters; tennis players; and squash players.

Trade painters were targeted through posters positioned in various commercial paint stores throughout Auckland. Nine stores were approached and supplied with a poster

which was placed in the kitchen area of the store, an area frequented by the trade painters. Each poster was left up for a period of 3 months.

Tennis and squash players were targeted through five tennis and squash clubs. A poster was positioned on the public notice board of tennis clubs in St Mary's Bay, Herne Bay, Westmere, and Point Chevalier. A poster was also placed in squash clubs in Herne Bay and Mt Albert. Posters were left up for a period of 3 months.

2.2 Online Advertising

Further advertising was conducted through an online participant recruitment site (<http://getparticipants.com>); paid advertising using an online social media network (<http://facebook.com>); and paid online advertising (<http://google.co.nz>).

2.2.1 GetParticipants

GetParticipants is an online website dedicated to recruiting participants for various projects throughout New Zealand. Interested participants are required to join GetParticipants before being able to apply to projects they are interested in. In August 2010 a project specific homepage was set up and initiated for this project, with the campaign running through until August 2011. The cost for GetParticipants was \$1 per applicant.

2.2.2 Google and Facebook Advertising

Both Google and Facebook advertising began in early 2011 targeting those people with shoulder pain and living in Auckland, New Zealand. Those interested in the study were re-directed to the projects GetParticipants homepage, however, they were not required to become a member of the site before applying for the study.

2.3 Editorial

In mid-2011 an editorial was sent to numerous sports clubs for inclusion in their member newsletters (Appendix B).

2.4 Initial Screening Process Prior to Assessment

Those individuals who responded to the advertising were contacted by the researcher via email and/or phone and asked eligibility questions in regards to the criterion of the project. If the person met the criteria and had symptoms that related to shoulder impingement syndrome they were asked to attend an appointment at the Unitec Student Osteopathic Clinic to further assess eligibility. Each person was asked to read through the participant information sheet and sign a consent form before proceeding with the eligibility assessment.

3. Results of Recruitment and Advertising

3.1 Results of Recruitment

In total 60 people applied to the study over the 12 month recruitment period. After the initial screening process 39 applicants were considered ineligible for the study or did not respond to further contact (Figure 1). These people did not attend the assessment session. The remaining 21 people were assessed with 10 deemed eligible for the study (Figure 2). The eligibility criteria are reported in the manuscript of this thesis.

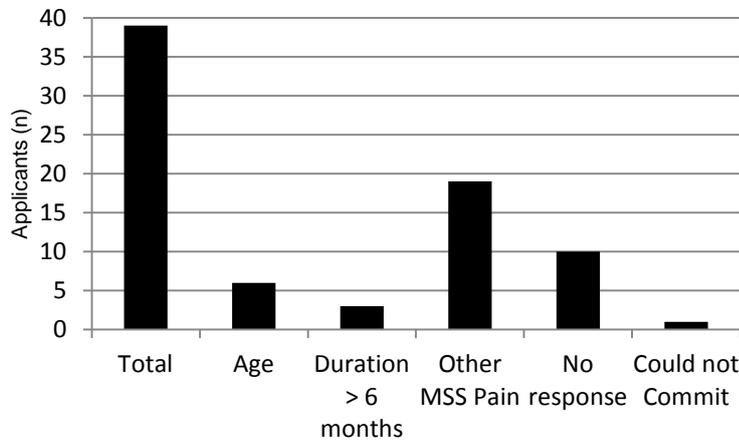


Figure 1 . Profile of the applicants ($n=39$) who were not considered for assessment following interview process. Abbreviations used: MSS = musculoskeletal.

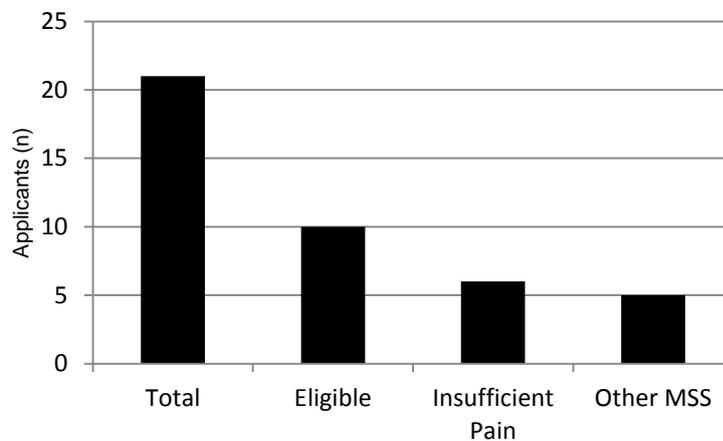


Figure 2. Profile of the applicants assessed and reasons found ineligible. Abbreviations used: MSS = musculoskeletal.

3.2 Results of Advertising

The success of each advertising method is demonstrated in Figure 3. The total cost of the advertising campaign was \$272 at \$27.20 per successful applicant although this did not include the cost of time and other researchers may need to consider this in preparing research budgets. The estimated time spent on recruitment was 65 hours.

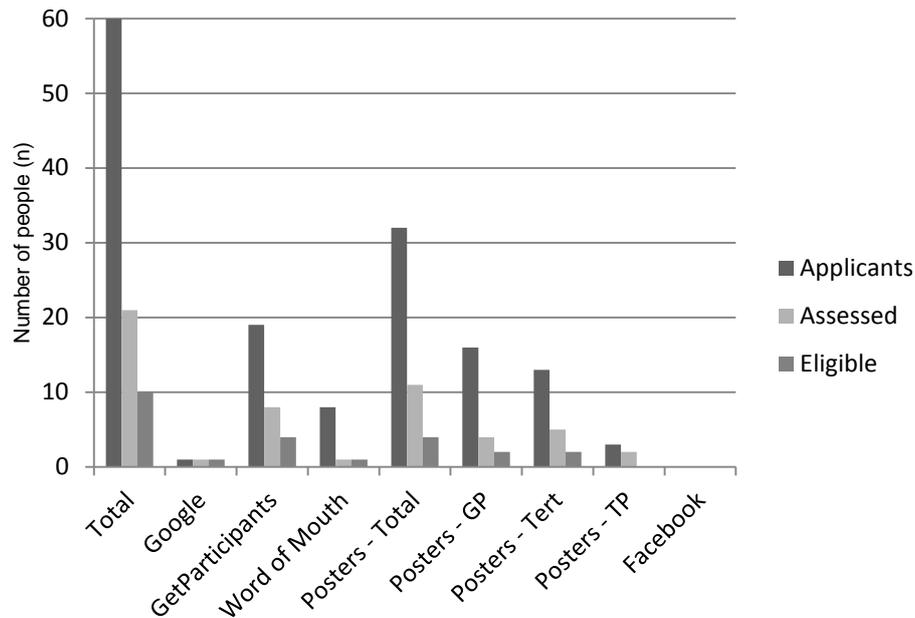


Figure 3. Profile of the relative success of each recruitment method. Abbreviations used: Posters – GP = general population; Posters Tert = tertiary students; Posters – TP = target population.

3.2.1 Posters

The greatest amount of interest came from posters, with 32 people applying for the study. Of the 32 applicants, 16 were from the general population, 13 from tertiary institutions, and only 3 from the target population. After the screening process 11 people were assessed for eligibility, with 4 eligible for the study. The cost of materials for the poster campaign was \$100 for the printing of 200 colour posters. Preparation of materials and distribution was estimated at 25 hours. The cost per successful applicant for this method of recruitment was \$25. This does not include the cost of time.

3.2.2 GetParticipants

In total, 427 GetParticipants members were notified about this project. The project homepage was viewed 1721 times over the 12 month period. Of those members notified, 19 applied to the study making the cost of the campaign \$19. After screening, 8 participants were asked to attend the assessment session, with 4 eligible for the study. This led to a cost per successful applicant of \$4.75.

3.2.3 Facebook

The Facebook campaign was undertaken with a total cost of \$153. Only 1 application was found through Facebook and met the eligibility criteria. The cost per successful applicant for Facebook advertising was \$153 making the total cost per successful applicant \$153.

3.2.4 Google

A small Google Adwords campaign was run but was discontinued due to a very low response rate.

3.2.5 Editorial

No applicants were found using this method of advertising.

3.2.6 Word of Mouth

Although not a formal recruitment strategy, eight applicants were found with word of mouth. Of these one was assessed and was eligible for the study.

Parts 3 and 4 of this report state the methods used to recruit participants and the results of each of the advertising methods. The next part will describe the effect that the low rate of recruitment had on both the design and reporting of data in this study.

4. Discussion

Due to the low rate of recruitment and subsequent inability to conduct between-group analysis, the design and reporting of this study was changed from a comparative RCT to a prospective case series. This part will describe the original intention of the study and why changes were made to the design and reporting.

4.1 Changes in Experimental Design and Reporting

The design originally proposed for this project was an RCT comparing an intervention group with a control group. After 12 months of recruitment it became apparent that it was not viable to report the study as an RCT therefore alternate research designs were considered. Due to the low rate of recruitment the two intervention groups could not be used for comparisons and grouping them for analysis was not possible due to small sample size. The clinical outcome of each participant was therefore considered and reported individually using the template of a prospective case study.

4.2 Final Form of Reporting of Study

The final design and reporting of this study was that of a prospective case series, but with inherent compromises due to the legacy of the original RCT design. Like an SSRD the study involved three phases: a baseline phase; an intervention phase; and a post-intervention phase. Unlike regular SSRD's, however, the baseline phase consisted of only 3 measurements rather than the 5 recommended by Backman & Harris (1999). The study also did not continue to take measurements during the intervention phase due to the original RCT design; therefore individual responses *during* the intervention phase were lost. Like an RCT the effect of treatment was established by measurements taken immediately following the intervention phase.

5. Conclusion

This section of the thesis was reported so as to assist future researchers to make informed decisions about both study design and marketing strategies for their project. It described in detail the strategies used during the recruitment process and the results obtained from each strategy. The main finding of this section was that a dedicated research recruitment website provided both the greatest number of participants and the most cost-effective form of recruitment of any strategies used.

Unfortunately the rate of recruitment was slower than anticipated therefore the original intentions of study design and data reporting were altered. This section described the changes that were made to both the design and reporting of the study and it is hoped the compromises made will help future researchers facing a similar predicament. It is suggested that careful consideration be given to: the prevalence of the target condition within the population; time and resources at the researcher's disposal that can be used for recruitment and the most feasible number of participants expected to be recruited with these resources; and an appropriate research design that best suits the expected number of participants.

6. References

- Backman, C. L., & Harris, S. R. (1999). Case studies and single system research: Comparisons and contrasts 1. *American Journal of Physical Medicine & Rehabilitation, 78*(2), 170-175.
- Bang, M. D., & Deyle, G. D. (2000). Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. *Journal of Orthopaedic and Sports Physical Therapy, 30*(3), 126-137.
- Boyles, R. E., Ritland, B. M., Miracle, B. M., Barclay, D. M., Faul, M. S., Moore, J. H., Koppenhaver, S.L., & Wainner, R.S. (2009). The short-term effects of thoracic spine thrust manipulation on patients with shoulder impingement syndrome. *Manual Therapy, 14*(4), 375-380.
- Conroy, D. E., & Hayes, K. W. (1998). The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. *Journal of Orthopaedic and Sports Physical Therapy, 28*(1), 3-14.
- Domholdt, E. (2005). *Rehabilitation research: principles and applications* (3rd ed.). St. Louis, Mo.: Elsevier Saunders.
- Faul, R.F., Erdfelder, E., Buchner, A., & Lang, A.G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods, 41*, 1149-1160.
- Leclerc, A., Chastang, J.F., Niedhammer, I., Landre, M.F., & Roquelaure, Y., (2004). Incidence of shoulder pain in repetitive work. *Journal of Occupational and Environment Medicine, 61*(1), 39-44.

- Magnusson, M. L., & Pope, M. H. (1998). A review of the biomechanics and epidemiology of working postures (it isn't always vibration which is to blame!). *Journal of Sound and Vibration*, 215(4), 965-976.
- Roy, J. S., Moffet, H., Hebert, L. J., Lirette, R. (2009). Effect of motor control and strengthening exercises on shoulder function in persons with impingement syndrome: A single-subject study design. *Manual Therapy*, 14(2), 180-188.
- Saks, M., & Allsop, J. (2007). *Researching health: Qualitative, quantitative and mixed methods*. London, United Kingdom: SAGE Publications Ltd.
- Sanders, G. (2003). Single system research designs in osteopathy. *Journal of Osteopathic Medicine*, 6(1), 19-23.
- Sim, J. (1995). The external validity of group comparative and single system studies. *Physiotherapy*, 81(5), 263-270.

Section 3: Manuscript

The effect of home-exercise with and without additional osteopathic treatment for those with shoulder impingement syndrome

Note:

This manuscript has been prepared in accordance with the Guide for Authors for the journal *Manual Therapy* [See Appendix G for Guide for Authors]. For the purposes of completion of this thesis some guidelines from *Manual Therapy* have not been followed. The instructions require a limit 3500 words. This limit has been exceeded here to allow full and evaluative discussion of the results in this thesis.

1. Abstract

The aim of this prospective case series was to document the outcome of a home-exercise program used alone and combined with a semi-standardised osteopathic treatment plan for those with shoulder impingement syndrome. Six participants with shoulder impingement were randomised into either a home-exercise group ($n=3$) or osteopathic group ($n=3$) and were followed during the ten week study period. All participants completed a 6-week home-exercise program aimed at centering the humeral head within the glenoid fossa and received 6 supervised training sessions. In addition, participants in the osteopathic group received 6 osteopathic treatments. Shoulder pain and function was measured using the Shoulder Pain and Disability Index (SPADI), Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure, and the Numeric Pain Rating Scale (NPRS) during physical examination of the shoulder. Outcome measures were taken at three baseline measurements, after the final intervention, and at a 2-week follow-up session. Clinically meaningful change was defined as a pre-post reduction greater than the minimal clinically important difference (MCID) for each respective outcome measure. All participants demonstrated clinically meaningful change for the SPADI, DASH, and NPRS for both the Neer and Hawkins impingement tests at post-intervention and 2-week follow-up. Clinically meaningful change was demonstrated at the 2-week follow-up for five participants for the painful arc test, five participants for the empty can test, one participant for the active-resisted internal rotation test, and four participants for the active-resisted external rotation test. The results of this study suggest that a home-exercise program with the aim of centering the humeral head within the glenoid fossa is associated with clinically meaningful improvements in shoulder pain and function when used alone and in conjunction with osteopathic treatment.

2. Introduction

Shoulder pain is a common complaint presenting to primary healthcare providers (van der Windt et al., 1995) with point prevalence reported to range from 6.9% to 26% and lifetime prevalence from 6.7% to 67% (Luime et al., 2004). When specific diagnoses of shoulder pain have been reported, shoulder impingement syndrome accounts for over half of all shoulder complaints (van der Windt et al., 1995). Shoulder impingement syndrome has been defined as mechanical compression of structures within the subacromial space (Bigliani et al., 1991) between the head of the humerus and the coracoacromial arch during glenohumeral joint elevation (Michener et al., 2003). Shoulder impingement syndrome is associated with subacromial bursitis, rotator cuff tears and tendinopathy (Valadie III et al., 2000), and leads to pain and functional disability of the shoulder complex (Chipchase et al., 2000). Contributors to the development of impingement include: poor co-activation of the rotator cuff muscles (Lewis et al., 2005; Myers et al., 2009; Diederichsen et al., 2009); altered scapular biomechanics during arm elevation (Ludewig and Cook, 2000; Moraes et al., 2008); increased forward head posture and impaired thoracic extension (Lewis et al., 2001); and altered anatomical morphology of the acromion (MacGillivray et al., 1998).

In New Zealand, evidence-based clinical practice guidelines for the treatment of soft tissue injuries of the shoulder advocate a trial of non-operative treatment before surgery is considered (The Accident Compensation Corporation, 2004). Non-operative treatment options of shoulder impingement syndrome typically include combinations of rest, activity modification, anti-inflammatory medication, simple analgesics, heat and ice, and injection of corticosteroids into the subacromial space (Conroy and Hayes, 1998; The Accident Compensation Corporation, 2004). Additionally, exercise prescription has been recommended as a treatment option and has been extensively researched in the literature. Studies have reported reduced shoulder pain and functional disability following exercise prescription said to influence: motor control of the rotator cuff (Dickens et al., 2005; Roy et al., 2009); shoulder range of motion (Bang and Deyle, 2000; Ludewig and Borstad, 2003; Kachingwe et al., 2008); and strength of

the rotator cuff and scapular stabilisers (Morrison et al., 1997; Bang and Deyle, 2000; Ludewig and Borstad, 2003; Kachingwe et al., 2008; Lombardi et al., 2008; Roy et al., 2009). Comparative results have been demonstrated between supervised and home based exercise programs (Walther et al., 2004). Walther et al. employed both supervised exercise and home-exercise intervention to influence the position of the humeral head within the glenoid fossa. The interventions were based on the premise that strengthening muscles that depress the humeral head centre the humeral head within the glenoid fossa and thus reduce impingement within the sub-acromial space. Altered position of the humeral head due to impaired co-activation of the rotator cuff during arm elevation is a recognised aetiology of shoulder impingement syndrome (Myers et al., 2009).

Shoulder impingement syndrome is commonly treated non-operatively through the use of manual therapy techniques (Bang and Deyle, 2000). Manual therapy used alone (Musil, 2006; Boyles et al., 2009; Hidalgo-Lozano et al., 2011) or in addition to shoulder exercise prescription (Conroy and Hayes, 1998; Bang and Deyle, 2000; Kachingwe et al., 2008; Tate et al., 2010; Senbursa et al., 2011), has been reported to improve patient reported symptoms associated with shoulder impingement syndrome. It is known that manual therapy provides additional benefits when used as an adjunct to exercise prescription (Kromer et al., 2009; Kuhn, 2009) however a comparative randomised controlled trial to directly compare exercise prescription with manual therapy is yet to be reported.

Osteopathic treatment uses a wide range of manual therapy techniques including joint mobilisation, soft-tissue mobilisation, spinal manipulation and mobilisation.

Osteopathy has been shown to be of clinical benefit for several disorders including: neck pain (Fryer et al., 2005); chronic lower back pain (Licciardone et al., 2005); and intermittent claudication (Lombardini et al., 2009). To date, there appears to be only one study that investigated the effectiveness of osteopathy for shoulder impingement syndrome (Musil, 2006). Musil compared osteopathic treatment against a standardised

exercise program that sought to strengthen muscles of the rotator cuff and scapular stabilisers. Although Musil claims improvement following osteopathic treatment, weaknesses in reporting of methods and results preclude interpretation of the findings. Notwithstanding these weaknesses of reporting, Musil's results appear promising and further investigation into the treatment of shoulder impingement syndrome with osteopathic treatment is warranted. Therefore, the aim of this study is to investigate the effect of a home-exercise program with and without the addition of a semi-standardised osteopathic treatment protocol on clinical measures of pain and disability in those with shoulder impingement syndrome.

3. Methods

3.1 Design

A prospective case series was conducted to measure the effect of a home-exercise program with and without the addition of osteopathic treatment for the treatment of shoulder impingement syndrome. The design is illustrated in Figure 1:

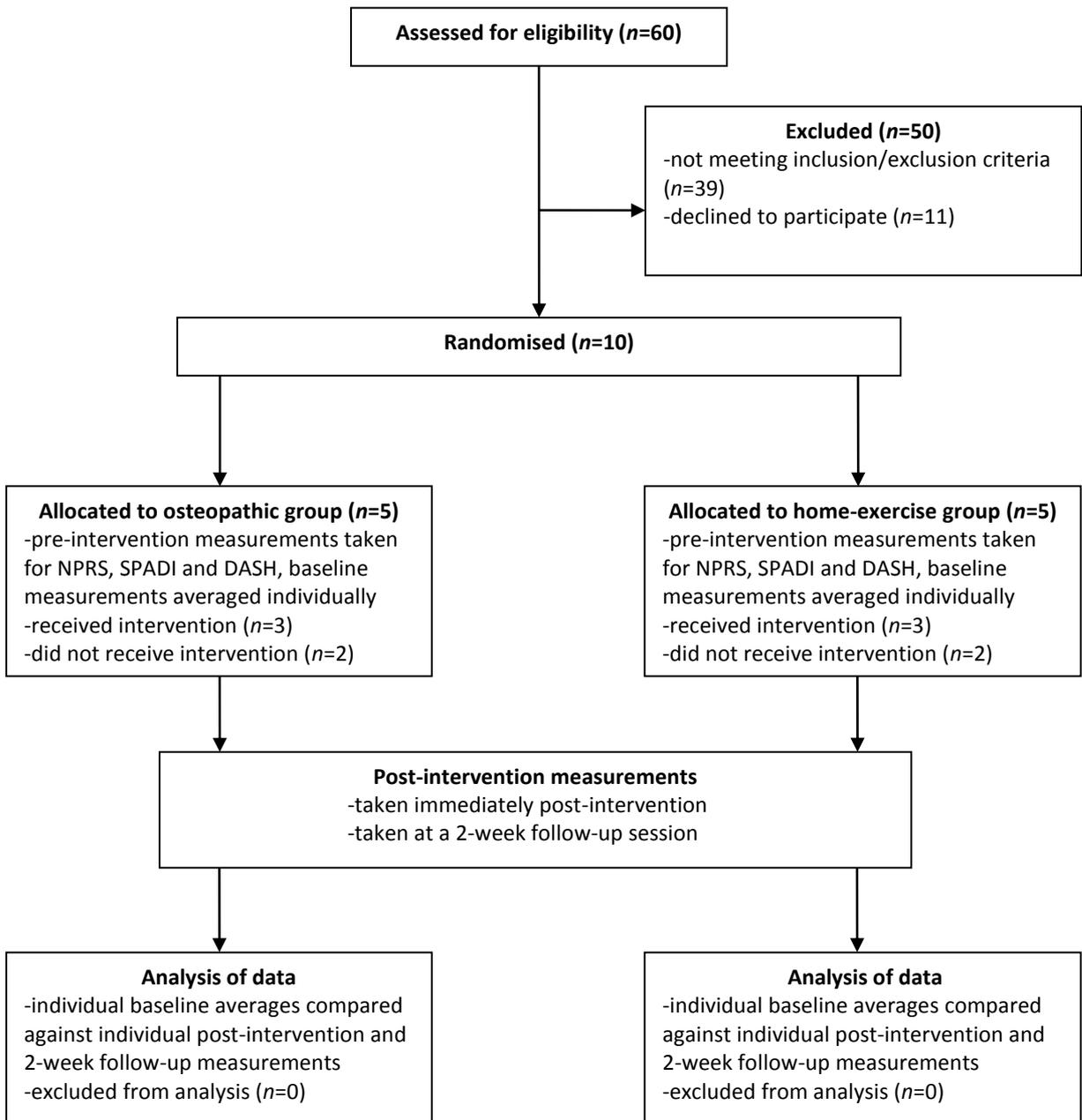


Figure 1. Flowchart of study design. Abbreviations NPRS = numeric pain rating scale; SPADI = shoulder pain and disability index; DASH = disability of the arm, shoulder and hand outcome measure.

3.2 Participants

3.2.1 Recruitment

Participants were recruited using: publically distributed posters and flyers; online advertising; and a press release. Posters targeted people in a variety of settings and included those of the general population, tertiary students, and a more specific at-risk population. The at-risk population were considered those that undertake repetitive activities over shoulder height during work or recreation (Leclerc et al., 2004), including trade painters, tennis players, and squash players. Further advertising was conducted through an online participant recruitment site (<http://getparticipants.com>); paid advertising using an online social media network (<http://facebook.com>); and paid online advertising (<http://google.co.nz>).

People who responded to advertising were contacted by email and telephone and completed an eligibility questionnaire regarding their shoulder pain. If suspected of suffering from shoulder impingement syndrome the person was asked to attend an appointment at the Unitec Student Osteopathic Clinic so as to formally assess their eligibility. Each person gave written and informed consent prior to participation. This study was approved by the Unitec Research Ethics Committee (Approval: 2010-1099).

3.2.2 Eligibility Assessment

The following inclusion and exclusion criteria were used to determine eligibility for enrolment. The eligibility assessment was conducted by the lead researcher.

Inclusion Criteria:

1. Aged between 18-40 years of age
2. Symptoms present for 6 months or less
3. Satisfy the diagnostic criteria for shoulder impingement syndrome as described by Bang and Deyle (2000). Participants must have reported pain of $\geq 3/10$ on

the NPRS during at least one of the tests in Category 1; and $\geq 3/10$ on the NPRS in at least one of the tests from Category 2; and 3.

Category 1:

Neer test

Hawkins test

Category 2:

Active abduction of shoulder

Painful arc test

Category 3:

Active resisted tests of the rotator cuff

Internal rotation

External rotation

Empty can

Exclusion Criteria:

1. Trauma or surgery to the symptomatic shoulder within the past 12 months
2. Currently receiving treatment on the symptomatic shoulder or spine
3. Symptoms associated with other disorders of the shoulder such as: osteoarthritis of the gleno-humeral joint, frozen shoulder, recurrent dislocation, suspected fracture, acromio-clavicular pain, suspected partial or full rotator cuff muscle tear, and cervical radiculopathy.

Those included in the study were randomly assigned to either the osteopathic group or the home-exercise group using an online random sequence generator (<http://random.org>).

3.3 Outcome Measures

Pain and disability arising from shoulder impingement syndrome was measured using the Shoulder Pain and Disability Index (SPADI)(Roach et al., 1991), and the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure (The DASH Outcome Measure, 2010). The NPRS (Turk et al., 1993) was measured during the Neer test, Hawkins test, painful arc test, empty can test, and active-resisted internal/external rotation of the gleno-humeral joint. Three baseline measurements were taken over an initial 2-week period prior to the intervention phase. Measurements were taken immediately post-intervention and at a 2-week follow-up session.

3.3.1 Shoulder Pain and Disability Index

The SPADI is a self-reported, 13-item questionnaire consisting of 5 questions related to pain experienced over the past week and 8 questions related to disability experienced over the past week (Roach et al., 1991). An 11-point scale was used for each item with participants asked to rate their pain whilst performing daily activities, and the difficulty in performing those activities.

It has been reported that a 13-point shift is required for there to be confidence that a minimal clinically important change has occurred (Schmitt and Di Fabio, 2004). The SPADI has a high sensitivity to change in score, and an acceptable level of test-retest reliability for people with shoulder impingement (Cloke et al., 2005). The SPADI has been shown to have high validity in assessing a person's level of shoulder pain and disability (MacDermid et al., 2006), and has been used in previous studies investigating shoulder impingement syndrome (Cloke et al., 2005; Kachingwe et al., 2008; Roy et al., 2008; Boyles et al., 2009; Roy et al., 2009; Kromer et al., 2010).

3.3.2 Disability of the Arm, Shoulder and Hand

The DASH outcome measure is a 30-item self-reported questionnaire that measures symptoms and degree of function related to a disorder in the upper extremity (The

DASH Outcome Measure, 2010). A 5-point scale was used for each question with participants asked to rate their ability to perform certain activities of daily living.

The DASH outcome measure is demonstrated to be a reliable and valid measure of disability in those complaining of upper extremity dysfunction (Kitis et al., 2009), with the MCID calculated at a 10-point shift (Schmitt and Di Fabio, 2004). The DASH has been used in previous studies involving manual therapy and exercise prescription for shoulder impingement syndrome (Lombardi et al., 2008; Roy et al., 2008, Tate et al., 2010).

3.3.3 Numeric Pain Rating Scale

Pain on overhead activities was measured using an 11-point numeric pain rating scale (NPRS) for pain, whilst the patient performs the Neer, Hawkins, painful arc, and empty can tests, and active-resisted internal/external rotation of the gleno-humeral joint. The NPRS ranges from 0 for “no pain”, to 10 for “worst possible pain” (Turk et al., 1993). The NPRS scale has been shown to be a reliable and valid measure of pain intensity (Price et al., 1994). A reduction of 2 points or 30% on the NPRS is needed to achieve MCID (Farrar et al., 2001).

3.3.4 Physical Examination Tests for Shoulder Impingement

The Neer, Hawkins, and painful arc tests are commonly used to diagnose shoulder impingement syndrome (Valadie III et al., 2000; Park et al., 2005). The Neer test involves full passive forward elevation of the shoulder until the patient reports pain (Park et al., 2005), whilst the Hawkins test combines forward flexion of the gleno-humeral joint to 60° combined with full internal rotation (Tucker et al., 2011). Reproduction of pain in the shoulder is said to indicate impingement syndrome (Valadie III et al., 2000). The painful arc test is described as active elevation of the arms in the scapular plane (Park et al., 2005), with pain indicative of shoulder impingement syndrome experienced between 60° and 120° of abduction (Calis et al., 2000; Cloke et

al., 2008). The Neer, Hawkins and painful arc tests have a sensitivity of 88%, 92%, and 32% respectively (Calis et al., 2000). Although the painful arc test has a low sensitivity, it has a high specificity of 80%, compared to the Neer test at 30%, and the Hawkins test at 25% (Calis et al., 2000).

3.4 Intervention

Participants of both the home-exercise group and the osteopathic group completed a 6-week home-exercise program as described by Walther et al. (2004) and outlined below. In addition to the home-exercise program participants within the osteopathic group received an additional 6 osteopathic treatments over the same period.

3.4.1 Home-exercise Intervention

The home-exercise program (see Appendix) was run over the 6-week intervention phase. Participants were asked to complete a home-exercise program that has been demonstrated to be effective in reducing symptoms associated with shoulder impingement syndrome (Walther et al., 2004). Each participant received a laminated copy of the home exercise program that included illustrations and written instructions. The home-exercise program was based on the premise that strengthening the depressors of the humeral head centres the head within the glenoid fossa thereby reducing impingement within the sub-acromial space. The home-exercise program also included strengthening exercises for muscles of scapular stabilisation, and stretches to the gleno-humeral capsule. Participants were provided with an elastic resistance band to use in exercises A to E within the program.

Participants were asked to perform the exercise program 5 days per week over the 6-week intervention phase, with exercises expected to take 15 minutes per day.

Participants were asked to stop the home-exercise program at the end of the intervention so the short to medium effect of the intervention could be evaluated.

Participants were provided with an exercise diary and were asked to record when they

performed each exercise session. The exercise diary provided a record of self-reported adherence to the program.

Participants in both the home-exercise group and osteopathic group received 6 supervised training sessions during the intervention phase. Participants were able to have any questions or concerns regarding the home-exercise program addressed during the supervised training session.

3.4.2 Osteopathic Intervention

The osteopathic intervention involved 6 treatment sessions over the 6-week intervention period. Participants were offered free treatment by the lead researcher, an osteopathic student practitioner. The initial session was 90-minutes in duration and included a full clinical evaluation. Subsequent osteopathic sessions were 45-minutes. The practitioner was a post-graduate osteopathic student and was supervised by clinical tutors currently practising as osteopaths in New Zealand.

The osteopathic intervention consisted of a combination of osteopathic techniques commonly used in clinical settings. The techniques have previously been used in manual therapy studies involving shoulder impingement syndrome (Conroy & Hayes, 1998; Bang & Deyle, 2000; Boyles et al., 2009; Roy et al., 2009), and a study using a semi-standardised osteopathic treatment plan (Fryer et al., 2004). The practitioner was not provided with a structured treatment plan but was given guidelines to work within at their own clinical judgement. Treatment addressed dysfunction of the lumbar, thoracic and cervical spine, joints of the shoulder girdle, muscles involved in scapular stabilisation, and muscles concerned with movement of the gleno-humeral joint. Full clinical notes were maintained for each consultation. Osteopathic techniques used were those described by Ward (2003) and Hartman (2001)(see Appendix).

3.5 Data Analysis

A mean value for each outcome measure and for each participant was calculated for the baseline phase. Comparisons were then made between baseline, post-intervention, and 2-week follow-up measurements using the MCID for the SPADI, DASH, and NPRS. Meaningful change was operationally defined to be a pre-post reduction greater than or equal to the MCID for each outcome measure. Plots were constructed to visually represent these data.

4. Results

Ten participants were eligible for the study. Two participants dropped out prior to the commencement of the intervention and two withdrew during the intervention phase. In each case, drop outs were due to time constraints. In total six participants completed the intervention phase and attended the 2-week follow-up measurement session (osteopathy $n=3$, home-exercise $n=3$).

4.1 Shoulder Pain and Disability Index

All six of the participants showed a reduction that achieved the MCID (13-point shift) for the SPADI at the post-intervention measurement and at the 2-week follow-up session when compared against the baseline average (Figure 2). For the pain section of the SPADI, all six participants demonstrated a reduction that achieved the MCID at both the post-intervention and 2-week follow-up (Figure 3). For the disability section of the SPADI, four of the six (P2, P4, P5 and P6) demonstrated a reduction that achieved the MCID at the post-intervention measurement and five (all but P3) at the 2-week follow-up (Figure 4).

4.2 Disabilities of the Arm, Shoulder and Hand Outcome Measure

A reduction that met the MCID for the DASH (10-point shift) was demonstrated in all six of the participants both at the post-intervention and 2-week follow-up measurement sessions (Figure 5). Two of the participants (P4 and P5) showed an increase in DASH scores from post-intervention to 2-week follow-up, yet still demonstrated a reduction greater than the MCID when compared against the baseline average. The remaining four participants demonstrated further reductions in DASH score from post-intervention to 2-week follow-up.

4.3 Numeric Pain Rating Scale

At post-intervention and 2-week follow-up measurement sessions all six of the participants demonstrated a reduction that met the MCID (2-point shift) for the NPRS when both the Neer (Figure 6) and Hawkins (Figure 7) impingement tests were performed. For the Neer test, four of the six participants (P2, P3, P5 and P6) demonstrated an increase of 1 to 3 points on the NPRS from post-intervention to 2-week follow-up, although all remained within the MCID when compared against baseline. For the Hawkins test four of the participants (P2, P3, P5, and P6) maintained their level of pain and two (P1 and P4) demonstrated a reduction of 1 point from post-intervention to 2-week follow-up.

For the painful arc test, five of the participants (all but P1) demonstrated reductions in NPRS to the MCID level from baseline to post-intervention to 2-week follow-up (Figure 8). The remaining participant (P1) had a baseline average of $<2/10$ therefore was unable to reach a significant reduction due to the “floor effect”.

For the empty can test, all six of the participants showed a reduction greater than the MCID on the NPRS at the post-intervention measurement (Figure 9). One participant (P5) demonstrated a 4 point increase on the NPRS from post-intervention to 2-week follow-up. Participant 5 therefore did not have a MCID change when the baseline average was compared against the 2-week follow-up measurement.

For the NPRS during active-resisted internal rotation, three of the participants (P2, P3 and P5) achieved a reduction greater than the MCID at post-intervention measurement (Figure 10). Only one participant (P3) maintained that reduction below the MCID at the 2-week follow-up measurement. One participant (P5) again demonstrated an increase of 4 points on the NPRS from post-intervention to 2-week follow-up, with the baseline to 2-week follow-up change failing to reach the MCID. Two participants (P1 and P4) had baseline averages $<2/10$ and were therefore unable to achieve the MCID.

For NPRS during active-resisted external rotation, four of the participants (P2, P3, P5 and P6) exhibited reductions greater than the MCID at both the post-intervention and 2-week follow-up measurements (Figure 11). Three of the four participants (P2, P5, P6) either maintained or demonstrated a further reduction of 1 to 2 points on the NPRS from post-intervention to 2-week follow-up, while the other (P3) demonstrated an increase of 1 point from post-intervention to 2-week follow-up. The remaining two participants (P1 and P4) had baseline averages <2/10 and were therefore unable to achieve the MCID for the NPRS.

4.4 Self-reported Adherence

Home-exercise diaries were collected at the conclusion of the intervention phase. Three of the participants (P2, P3 and P5) reported 100% adherence to the program, whilst the remaining three participants (P1, P4 and P6) reported greater than 90% adherence.

5. Discussion

5.1 Overview

The aim of this study was to document the outcomes following a home-exercise program combined with a semi-standardised osteopathic treatment plan for those with shoulder impingement syndrome. This study also sought to investigate the effect of a home-exercise program in isolation. The exercise program was based on the premise of centering the humeral head within the glenoid fossa. Osteopathic treatment has been demonstrated to achieve positive results for those with shoulder impingement (Musil, 2006), although the low quality reporting of this study precluded interpretation of the findings. The results of the current study indicate that osteopathic treatment, when used as an adjunct to home-exercise, is associated with clinically meaningful improvements in shoulder pain and disability. Clinically meaningful reductions in shoulder pain and disability were also demonstrated following the home-exercise program.

5.2 Home-exercise

The findings of this study are consistent with the current evidence that home-exercise programs can be effective in reducing levels of self-reported pain and disability in people with shoulder impingement syndrome (Ludewig and Borstad, 2003; Walther et al., 2004). The home-exercise program in this study was adapted from Walther et al. (2004), with the intervention phase reduced from 12 to 6 weeks. Although the home-exercise intervention was delivered over an abbreviated period, clinically meaningful reductions were still observed for disability (SPADI, DASH) and pain (NPRS) during provocative shoulder tests. The appropriate intervention dose for home-exercise is not clear in the literature, however the results of the current study suggest a shorter duration may be sufficient.

5.3 Home-exercise vs Supervised Exercise

Supervised exercise prescription is a well-established and effective form of treatment for shoulder impingement syndrome (Morrison et al., 1997; Bang and Deyle, 2000; Haahr et al., 2005; Kachingwe et al., 2008; Lombardi et al., 2008; Roy et al., 2009). Supervised exercise does, however, require intensive practitioner time and related expense. To date, the duration of supervised exercise interventions reported in the published literature ranges from 4 weeks (Roy et al., 2009) to 3-6 months (Brox et al., 1999), and the number of sessions from 6 (Kachingwe et al., 2008), to 30 or more (Brox et al., 1999; Walther et al., 2004). In comparison, home-exercise programs have used as little as 2 training sessions over 8 weeks (Ludewig and Borstad, 2003). The advantage of home-exercise is that it can require less contact with the practitioner and therefore may incur less cost to the patient or healthcare insurance provider. The lower cost of home-exercise does, however, need to be considered in light of the likelihood of lower adherence to home-exercise (Cox et al., 2003) which has been suggested to lead to poorer clinical outcomes in those with shoulder impingement (Ludewig and Borstad, 2003).

5.4 Adherence to Home-exercise

To promote adherence participants in the current study received a laminated home-exercise sheet with illustrations and written descriptions for each exercise to be performed and were provided with an exercise diary to record the completion of each exercise session. The self-reported adherence achieved during this study ranged from 90 to 100% for all participants. This is well above that found by Ludewig and Borstad (2003) who reported >75% adherence in only 9 of 34 participants completing a home-exercise program. It is unknown, however, how this compares to Walther et al. (2004) who reported only that participants in the home-exercise group “fulfilled the guidelines concerning the frequency of their exercises” but did not report the guidelines. It is recommended that future studies using home-exercise consistently report adherence data.

5.5 Exercise Prescription combined with Manual Therapy

A major limitation of case series designs is that comparisons cannot be validly made between interventions, therefore in this study no conclusion can be made about the possible benefit of osteopathic treatment in addition to exercise prescription compared to other interventions. The findings of this study do, however, seem promising as they are consistent with emerging evidence that exercise prescription combined with various forms of manual therapy (Conroy and Hayes, 1998; Bang and Deyle, 2000; Kachingwe et al., 2008; Tate et al., 2010), including osteopathy (Musil, 2006), improves self-reported levels of shoulder pain and disability.

5.6 Clinical Benefit of Exercise Prescription combined with Manual Therapy

It appears manual therapy in conjunction with exercise offers greater clinical benefit than that of exercise alone for the treatment of shoulder impingement syndrome (Conroy and Hayes, 1998; Bang and Deyle, 2000; Kachingwe et al., 2008). Liebensohn (1996) describes a theoretical model for the treatment of musculoskeletal disorders that combines both 'active' and 'passive' care for the management of subacute, recurrent, and chronic conditions. Liebensohn argues that no single form of treatment can adequately address the multi-causal aetiology of many musculoskeletal conditions. Combining passive manual therapy and active exercise prescription has become a common approach in treating a range of musculoskeletal disorders including low back pain (van Middelkoop et al., 2011), neck pain (Miller et al., 2010), and whiplash (Bronfort et al., 2001).

Given the complex aetiology of shoulder impingement syndrome (Michener et al., 2003) it is possible that there are recognisable aetiological subgroups of people who respond to different forms of treatment. If subgroups of shoulder impingement syndrome can be clinically recognised then this may present an opportunity for the development of clinical prediction rules and more appropriate matching of aetiology and therapy. For example, those with altered motor control of the scapular stabilisers

(Moraes et al., 2008) may be more responsive to active exercise approaches, while those with gleno-humeral capsule tightness (Hjelm et al., 1996) may be candidates for passive manual therapy. Due to the complex aetiology of shoulder impingement syndrome, multi-factorial interventions combining both active and passive treatment are appropriate.

The primary aims of the home-exercise program employed in this study were to 1) improve function of the rotator cuff and thereby centre the humeral head within the glenoid fossa (Myers et al., 2009); 2) improve gleno-humeral capsule tightness; and 3) strengthen the scapular stabilising muscles. In addition, the osteopathic practitioner applied manual therapy techniques to the shoulder girdle and related spinal segments and it has been reported that gleno-humeral joint mobilisation improves pain intensity when added to an exercise program (Conroy and Hayes, 1998; Kachingwe et al., 2008). Bialosky et al. (2009) propose a model that manual therapy inhibits pain perception via mechanical stimulation which initiates a cascade of local and neurological events.

High-velocity low-amplitude (HVLA) thrust technique was administered in this study with the aim of improving the quality and function of spinal segments (Hartman, 2001). Extension mobility of the thoracic spine is a vital component necessary to perform adequate active range of motion of the shoulder (Bullock et al., 2005; Lewis et al., 2005) with a flexed thoracic posture known to contribute to the development of shoulder impingement syndrome (Kebaetse et al., 1999). HVLA thrust improves range of motion of both the spine (Martinez-Segura et al., 2006) and shoulder (Strunce et al., 2009), and has been demonstrated to provide short-term improvements in pain and disability in those with shoulder impingement (Boyles et al., 2009).

5.7 Internal Validity

Clinically meaningful reductions in shoulder pain and disability were observed in participants following both osteopathic treatment and exercise prescription. Despite this temporal relationship between treatment and clinical improvement, a causal

relationship cannot be concluded due to limitations of the case series design. Causation is best determined using randomised controlled trials that decrease the likelihood of other extraneous factors that may account for observed improvement, such as natural resolution of condition. Some argue that the establishment of a stable baseline allows the individual to act as their own control (Sim, 1995) thereby strengthening inferences about causal relationship between the intervention and any observed change in dependent variables. In this study outcome measures were recorded over three baseline measurement sessions to demonstrate stability of shoulder symptoms prior to the intervention. A baseline phase of five measurements, as recommended by Logan et al. (2008), would further improve confidence in the stability of symptoms and therefore allow more confident attribution of treatment effect.

A weakness of this study is that the lead researcher carried out eligibility assessment, collection of data, and the administration of osteopathic treatment and home-exercise supervision. Although the use of a single researching practitioner obviously introduces bias, the design of the study is representative of the type of objective measures and combination of passive and active rehabilitation required by third party payers such as the Accident Compensation Corporation (The Accident Compensation Corporation, 2011). The use of a blinded assessor independent from the osteopathic practitioner would strengthen the internal validity of this study.

5.8 External Validity

The case series design of this study limits generalisation of results (Domholdt, 2005). A randomised controlled trial comparing osteopathic treatment and home-exercise prescription would provide results that could be generalised. In the hierarchy of evidence case series are considered to be a low form of evidence (Oxford Centre for Evidence-Based Medicine, 2011). Case series are, however, useful to inform the viability of more robust research designs including comparative RCT's. The results of this study are sufficiently promising to justify the consideration of a full RCT

5.9 Future Research

Although the home-exercise program sought to strengthen muscles of the rotator cuff and scapular stabilisers pre- and post-intervention measurements for muscle strength were not taken. Walther et al. (2004) reported no change in strength scores following their 12-week intervention a finding similar to that of Lombardi et al. (2008) who found little difference in strength variables between those completing 2 months of exercise prescription and a control group performing no exercise. Interestingly though, Bang and Deyle (2000) reported that the addition of manual therapy to exercise prescription achieved significantly greater improvements in strength over exercise prescription alone. Increased pain has been demonstrated to impair muscle strength (Henriksen et al., 2011). Bang and Deyle (2000) speculate that manual therapy reduces pain intensity and optimises the conditions in which strengthening exercises were performed. It was not clear whether the manual therapy was applied prior to or immediately following the exercise training. It would be useful to investigate the effect of order for application of manual therapy and exercise prescription as conventional clinical practice is to prescribe exercise subsequent to manual therapy.

6. Conclusion

This prospective case series documented clinically meaningful improvements in shoulder pain and disability following a 6-week home-exercise program based on the premise of centering the humeral head within the glenoid fossa. Clinically meaningful improvements were also observed when the home-exercise program was combined with a semi-standardised osteopathic treatment plan. Future research using a randomised controlled trial design should be conducted to investigate the effect of osteopathic treatment for shoulder impingement syndrome.

7. References

The Accident Compensation Corporation. The diagnosis and management of soft tissue shoulder injuries and related disorders, 2004. <http://www.acc.co.nz/providers/clinical-best-practice/acc-review/index.htm>; 2004 (accessed 27/9/2009).

The Accident Compensation Corporation. Guide to Outcome Measure Reporting. http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_communications/documents/guide/prd_ctrb118711.doc; 2011 (accessed 7/12/2011).

Bang MD, Deyle GD. Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. *Journal of Orthopaedic and Sports Physical Therapy* 2000; 30(3): 126-137.

Bialosky JE, Bishop MD, Price DD, Robinson ME, George SZ. The mechanisms of manual therapy in the treatment of musculoskeletal pain: a comprehensive model. *Manual Therapy* 2009; 14(5): 531-538.

Bigliani LU, Ticker JB, Flatow EL, Soslowky LJ, Mow VC. The relationship of acromial architecture to rotator cuff disease. *Clinic in Sports Medicine* 1991; 10(4): 823-838.

Boyles RE, Ritland BM, Miracle BM, Barclay DM, Faul MS, Moore JH, Koppenhaver SL, Wainner RS. The short-term effects of thoracic spine thrust manipulation on patients with shoulder impingement syndrome. *Manual Therapy* 2009; 14(4): 375-380.

Bronfort G, Evans R, Nelson B, Aker PD, Goldsmith CH, Vernon H. A randomized clinical trial of exercise and spinal manipulation for patients with chronic neck pain. *Spine* 2001; 26(7): 788-799.

- Brox JI, Gjengedal E, Uppheim G, Bohmer AS, Brevik JI, Ljunggren AE, Staff PH. Arthroscopic surgery versus supervised exercises in patients with rotator cuff disease (stage II impingement syndrome): a prospective, randomized, controlled study in 125 patients with a 2 and a half year follow-up. *Journal of Shoulder and Elbow Surgery* 1999; 8(2): 102-111.
- Bullock MP, Foster NE, Wright CC. Shoulder impingement: the effect of sitting posture on shoulder pain and range of motion. *Manual Therapy* 2005; 10(1): 28-37.
- Calis M, Akgun K, Birtane M, Karacan I, Calis H, Tuzun F. Diagnostic values of clinical diagnostic tests in subacromial impingement syndrome. *Annals of the Rheumatic Disease* 2000; 59(1): 44-47.
- Chipchase LS, O'Connor DA, Costi JJ, Krishnan J. Shoulder impingement syndrome: Preoperative health status. *Journal of Shoulder and Elbow Surgery* 2000; 9(1): 12-15.
- Cloke DJ, Lynn SE, Watson H, Steen IN, Purdy S, Williams JR. A comparison of functional, patient-based scores in subacromial impingement. *Journal of Shoulder and Elbow Surgery* 2005; 14(4): 380-384.
- Cloke DJ, Lynn SE, Watson H, Purdy S, Steen IN, Williams JR. A pilot randomized, controlled trial of treatment for painful arc of the shoulder. *Journal of Shoulder and Elbow Surgery* 2008; 17(1): S17-S21.
- Conroy DE, Hayes KW. The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. *Journal of Orthopaedic and Sports Physical Therapy* 1998; 28(1): 3-14.

Cox KL, Burke V, Gorely TJ, Beilin LJ, Puddey IB. Controlled Comparison of Retention and Adherence in Home- vs Center-Initiated Exercise Interventions in Women Ages 40–65 Years: The S.W.E.A.T. Study (Sedentary Women Exercise Adherence Trial). *Preventive Medicine* 2003; 36(1): 17-29.

Dickens VA, Williams JL, Bharna MS. Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. *Physiotherapy* 2005; 91(3): 159-164.

Diederichsen LP, Norregaard J, Dyhre-Poulsen P, Winther A, Tufekovic G, Bandholm T, Rasmussen LR, Krogsgaard M. The activity pattern of shoulder muscles in subjects with and without subacromial impingement. *Journal of Electromyography and Kinesiology* 2009; 19(5): 789-799.

The Disability of the Arm, Shoulder and Hand Outcome Measure. The DASH outcome measure.

http://www.dash.iwh.on.ca/assets/images/pdfs/dash_questionnaire_2010.pdf;

2010 (accessed 17/3/2010).

Domholdt, E. *Rehabilitation research: principles and applications* (3rd ed.). St. Louis, Mo.: Elsevier Saunders; 2005.

Farrar JT, Young Jr JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001; 94(2): 149-158.

Fryer G, Alvizatos J, Lamaro J. The effect of osteopathic treatment on people with chronic and sub-chronic neck pain: A pilot study. *International Journal of Osteopathic Medicine* 2004; 8(2): 41-48.

Haahr JP, Ostergaard S, Dalsgaard J, Norup K, Frost P, Lausen S, Holm EA, Andersen JH. Exercises versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up. *Annals of the Rheumatic Diseases* 2005; 64(5): 760-764.

Hartman L. *Handbook of osteopathic technique*. 3rd ed. Cheltenham, United Kingdom: Nelson Thornes Ltd; 2001.

Henriksen M, Rosager S, Aaboe J, Graven-Nielsen T, Bliddal H. Experimental knee pain reduces muscle strength. *The Journal of Pain* 2011; 12(4): 460-467.

Hidalgo-Lozano A, Fernandez-de-las-Penas C, Diaz-Rodriguez L, Gonzalez-Iglesias J, Palacios-Cena D, Arroyo-Morales M. Changes in pain and pressure pain sensitivity after manual treatment of active trigger points in patients with unilateral shoulder impingement: a case series. *Journal of Bodywork and Movement Therapies* 2011; 15(4): 399-404.

Hjelm R, Draper C, Spencer S. Anterior-inferior capsular length insufficiency in the painful shoulder. *The Journal of Orthopaedic & Sports Physical Therapy* 1996; 23(3): 216-222.

Kachingwe AF, Phillips B, Sletten E, Plunkett SW. Comparison of manual therapy techniques with therapeutic exercise in the treatment of shoulder impingement: A randomized controlled pilot clinical trial. *The Journal of Manual and Manipulative Therapy* 2008; 16(4): 238-247.

Kebaetse M, McClure P, Pratt NA. Thoracic position effect on shoulder range of motion, strength, and three-dimensional scapular kinematics. *Archives of Physical Medicine and Rehabilitation* 1999; 80(8): 945-950.

Kitis A, Celik E, Aslan UB, Zencir M. DASH questionnaire for the analysis of musculoskeletal symptoms in industry workers: a validity and reliability study. *Journal of Applied Ergonomics* 2009; 40(2): 251-255.

Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CHG. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. *Journal of Rehabilitation Medicine* 2009; 41(11): 870-880.

Kromer TO, de Bie RA, Bastiaenen CHG. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. *BMC Musculoskeletal Disorders*; 11(114). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2889850/pdf/1471-2474-11-114.pdf>; 2010 (accessed 3/4/2011).

Kuhn JE. Exercise in the treatment of rotator cuff impingement: A systematic review and a synthesized evidence-based rehabilitation protocol. *The Journal of Shoulder and Elbow Surgery* 2009; 18(1): 138-160.

Leclerc A, Chastang JF, Niedhammer I, Landre MF, Roquelaure Y. Incidence of shoulder pain in repetitive work. *Journal of Occupational and Environment Medicine* 2004; 61(1): 39-44.

Lewis JS, Green A, Dekel S. The aetiology of subacromial impingement syndrome. *Physiotherapy* 2001; 87(9): 458-469.

Lewis JS, Wright C, Green A. Subacromial impingement syndrome: the effect of changing posture on shoulder range of movement. *Journal of Orthopaedic and Sports Physical Therapy* 2005; 35(2): 72-87.

Licciardone JC, Brimhall AK, King LN. Osteopathic manipulative treatment for low back pain: a systematic review and meta-analysis of randomized controlled trials.

BMC Musculoskeletal Disorders, 4(6).

<http://www.biomedcentral.com/content/pdf/1471-2474-6-43.pdf>; 2005

(accessed 6/8/2011).

Liebenson C. Rehabilitation of the spine: a practitioner's manual. Baltimore, Maryland,

United States of America: Lippincott Williams & Wilkins; 1996.

Logan LR, Hickman RR, Harris SR, Heriza CB. Single-subject research design:

recommendations for levels of evidence and quality rating. Developmental

Medicine and Child Neurology 2008; 50(2): 99-103.

Lombardi Jr I, Magri AG, Fleury AM, da Silva AC, Natour J. Progressive resistance

training in patients with shoulder impingement syndrome: a randomized

controlled trial. Journal of Arthritis and Rheumatism 2008; 59(5): 615-622.

Lombardini R, Marchesi S, Collebrusco L, Vaudo G, Pasqualini L, Ciuffetti G, Brozzetti M,

Lupattelli G, Mannarino E. The use of osteopathic manipulative treatment as

adjuvant therapy in patients with peripheral arterial disease. Manual Therapy

2009; 14(4): 439-443.

Ludewig PM, Cook TM. Alterations in shoulder kinematics and associated muscle

activity in people with symptoms of shoulder impingement. Physical Therapy

2000; 80(3): 276-291.

Ludewig PM, Borstad JD. Effects of a home exercise programme on shoulder pain and

functional status in construction workers. Occupation and Environmental

Medicine 2003; 60(11): 841-849.

- Luime JJ, Koes BW, Hendriksen IJ, Burdorf A, Verhagen AF, Miedema HS, Verhaar JA. Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scandinavian Journal of Rheumatology* 2004; 33(2): 73-81.
- MacDermid JC, Solomon P, Prkachin K. The Shoulder Pain and Disability Index demonstrates factor, construct and longitudinal validity. *BMC Musculoskeletal Disorders*; 7 (12). <http://www.biomedcentral.com/content/pdf/1471-2474-7-12.pdf>; 2006 (accessed 9/8/2009).
- MacGillivray JD, Fealy S, Potter HG, O'Brien SJ. Multiplanar analysis of acromion morphology. *The American Journal of Sports Medicine* 1998; 26(6): 836-840.
- Martinez-Segura R, Fernandez-de-las-Penas C, Ruiz-Saez M, Lopez-Jimenez C, Rodriguez-Blanci C. Immediate effects on neck pain and active range of motion after a single cervical high-velocity low-amplitude manipulation in subjects presenting with mechanical neck pain: a randomized controlled trial. *The Journal of Manual and Manipulative Therapy* 2006; 29(7): 511-517.
- Michener LA, McClure PW, Karduna AR. Anatomical and biomechanical mechanisms of subacromial impingement syndrome. *Clinical Biomechanics* 2003; 18(5): 369-379.
- van Middelkoop M, Rubinstein SM, Kuijpers T, Verhagen AP, Ostelo R, Koes BW, van Tulder MW. A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *European Spine Journal* 2011; 20(1): 19-39.
- Miller J, Gross A, D'Sylva J, Burnie SJ, Goldsmith CH, Graham N, Haines T, Bronfort G, Hoving JL. Manual therapy and exercise for neck pain: A systematic review. *Manual Therapy* 2010; 15(4): 334-354.

Moraes GFS, Faria CDCM, Teixeira-Salmela LF. Scapular muscle recruitment patterns and isokinetic strength ratios of the shoulder rotator muscles in individuals with and without impingement syndrome. *The Journal of Shoulder and Elbow Surgery* 2008; 17(1): 48S-53S.

Morrison DS, Frogameni AD, Woodworth P. Non-operative treatment of subacromial impingement syndrome. *The Journal of Bone & Joint Surgery* 1997; 79(5): 732-737.

Musil, K. (2006). The treatment of the subacromial syndrome of the shoulder either by osteopathic treatment or by guided self-training. www.osteopathicresearch.com/paper_pdf/Anderl_engl.pdf; 2006 (accessed 15/9/2009).

Myers JB, Hwang J, Pasquale MR, Blackburn JT, Lephart SM. Rotator cuff coactivation ratios in participants with subacromial impingement syndrome. *Journal of Science and Medicine in Sport* 2009; 12(6): 603-608.

Oxford Centre for Evidence-Based Medicine. OCEBM Levels of Evidence Working Group. "The Oxford 2011 Levels of Evidence". <http://www.cebm.net/index.aspx?o=5653>; 2011 (accessed 10/01/2012).

Park HB, Yokata A, Gill HS, El Rassi G, McFarland EG. Diagnostic accuracy of clinical tests for the different degrees of subacromial impingement syndrome. *The Journal of Bone and Joint Surgery* 2005; 87(7): 1446-1455.

Price DD, Bush FM, Long S, Harkins SW. A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales. *Pain* 1994; 56(2): 217-226.

Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a Shoulder Pain and Disability Index. *Arthritis Care and Research* 1991; 4(4): 143-149.

Roy JS, Moffet H, McFadyen BJ. Upper limb motor strategies in persons with and without shoulder impingement syndrome across different speeds of movement. *Clinical Biomechanics* 2008; 23(10): 1227-1236.

Roy JS, Moffet H, Hebert LJ, Lirette R. Effect of motor control and strengthening exercises on shoulder function in persons with impingement syndrome: A single-subject study design. *Manual Therapy* 2009; 14(2): 180-188.

Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. *Journal of Clinical Epidemiology* 2004; 57(10): 1008-1018.

Senbursa G, Baltaci G, Atay A. The effectiveness of manual therapy in supraspinatus tendinopathy. *Acta Orthopaedica et Traumatologica Turcica* 2011; 45(3): 162-167.

Sim J. The external validity of group comparative and single system studies. *Physiotherapy* 1995; 81(5): 263-270.

Strunce JB, Walker MJ, Boyles RE, Young BA. The immediate effects of thoracic spine and rib manipulation on subjects with primary complaints of shoulder pain. *The Journal of Manual and Manipulative Therapy* 2009; 17(4): 230-236.

Tate AR, McClure PW, Young IA, Salvatori R, Michener LA. Comprehensive impairment-based exercise and manual therapy intervention for patients with subacromial impingement syndrome: a case series. *The Journal of Orthopaedic and Sports Physical Therapy* 2010; 40(8): 474-493.

Tucker S, Taylor NF, Green RA. Anatomical validity of the Hawkins-Kennedy test – a pilot study. *Manual Therapy* 2011; 16(4): 399-402.

Turk DC, Rudy TE, Sorkin BA. Neglected topics in chronic pain treatment outcome studies: determination of success. *Pain* 1993; 53(1): 3-16.

Valadie III AL, Jobe CM, Pink MM, Ekman EF, Jobe FW. Anatomy of provocative tests for impingement syndrome of the shoulder. *Journal of Shoulder and Elbow Surgery* 2000; 9(1): 36-46.

Walther M, Werner A, Stahlschmidt T, Woelfel R, Gohlke F. The subacromial impingement syndrome of the shoulder treated by conventional physiotherapy, self-training, and a shoulder brace: Results of a prospective, randomized study. *Journal of Shoulder and Elbow Surgery* 2004; 13(4): 17-23.

Ward RC. *Foundation for osteopathic medicine*. Philadelphia, Pennsylvania, United States of America: Lippincott Williams & Wilkins; 2003.

van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. *The British Journal of General Practice* 1995; 46(410): 519-523

8. Figures

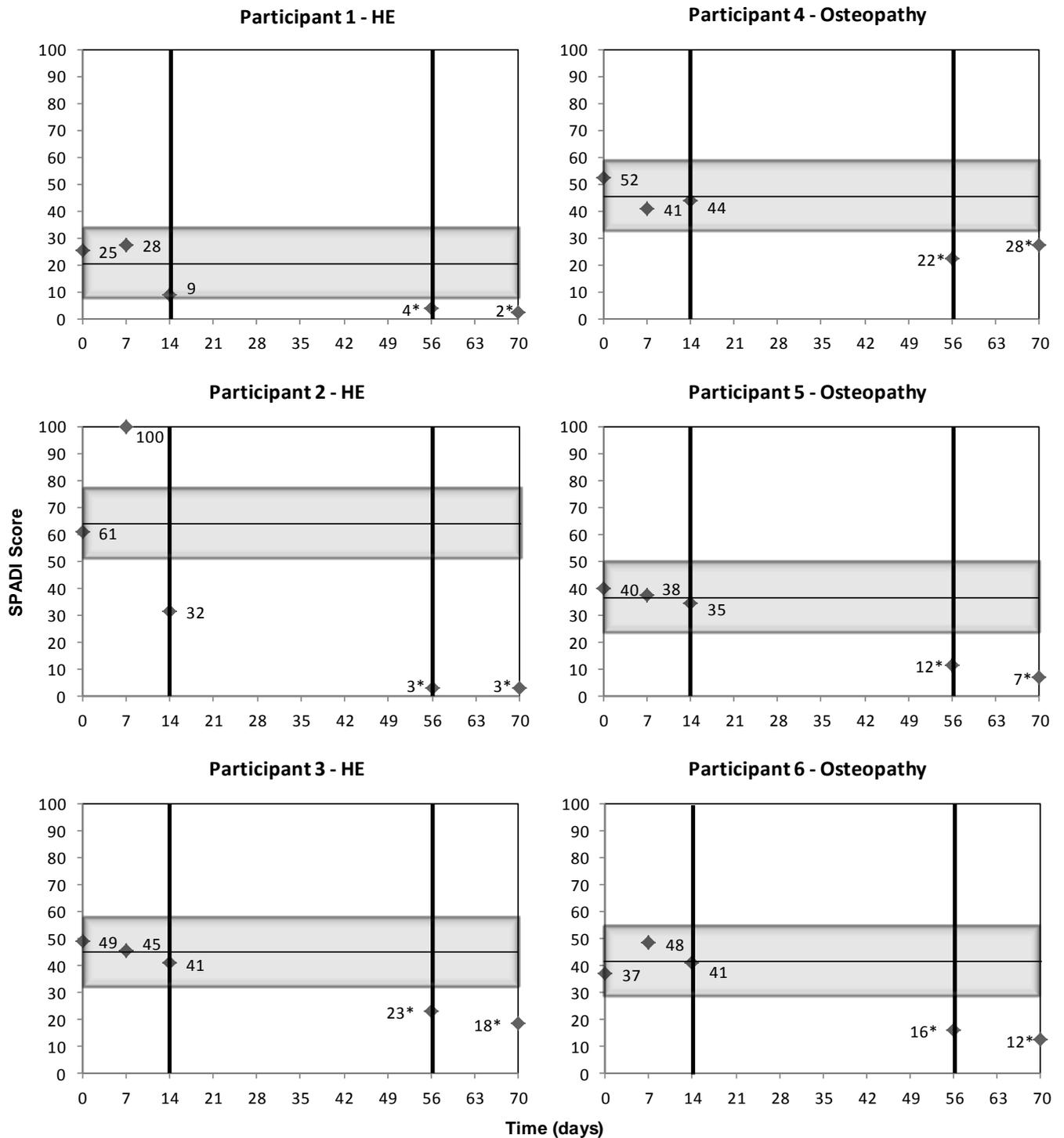


Figure 2. Profile of the SPADI scores. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

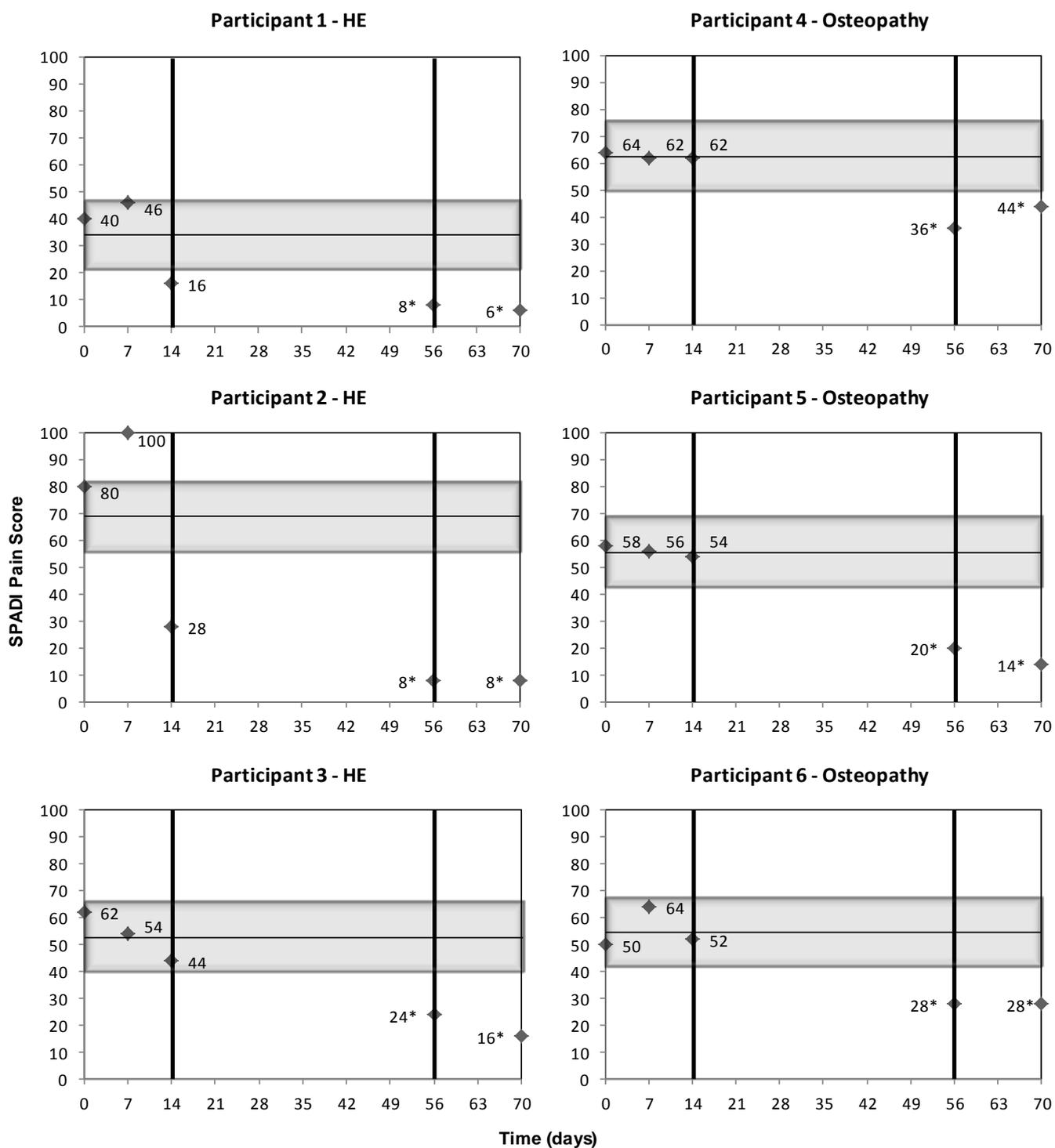


Figure 3. Profile of the SPADI scores – pain section. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

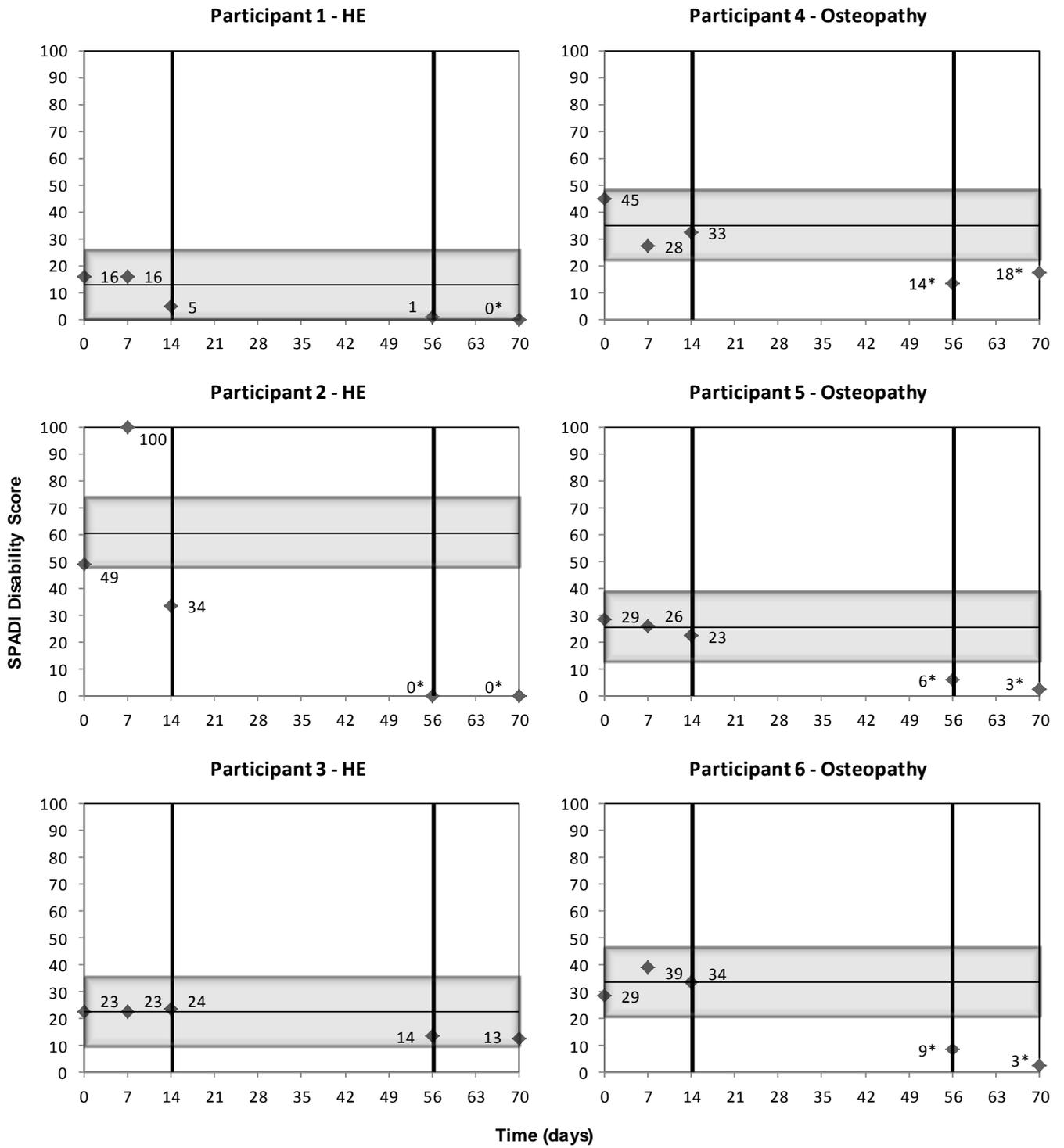


Figure 4. Profile of the SPADI scores – disability section. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

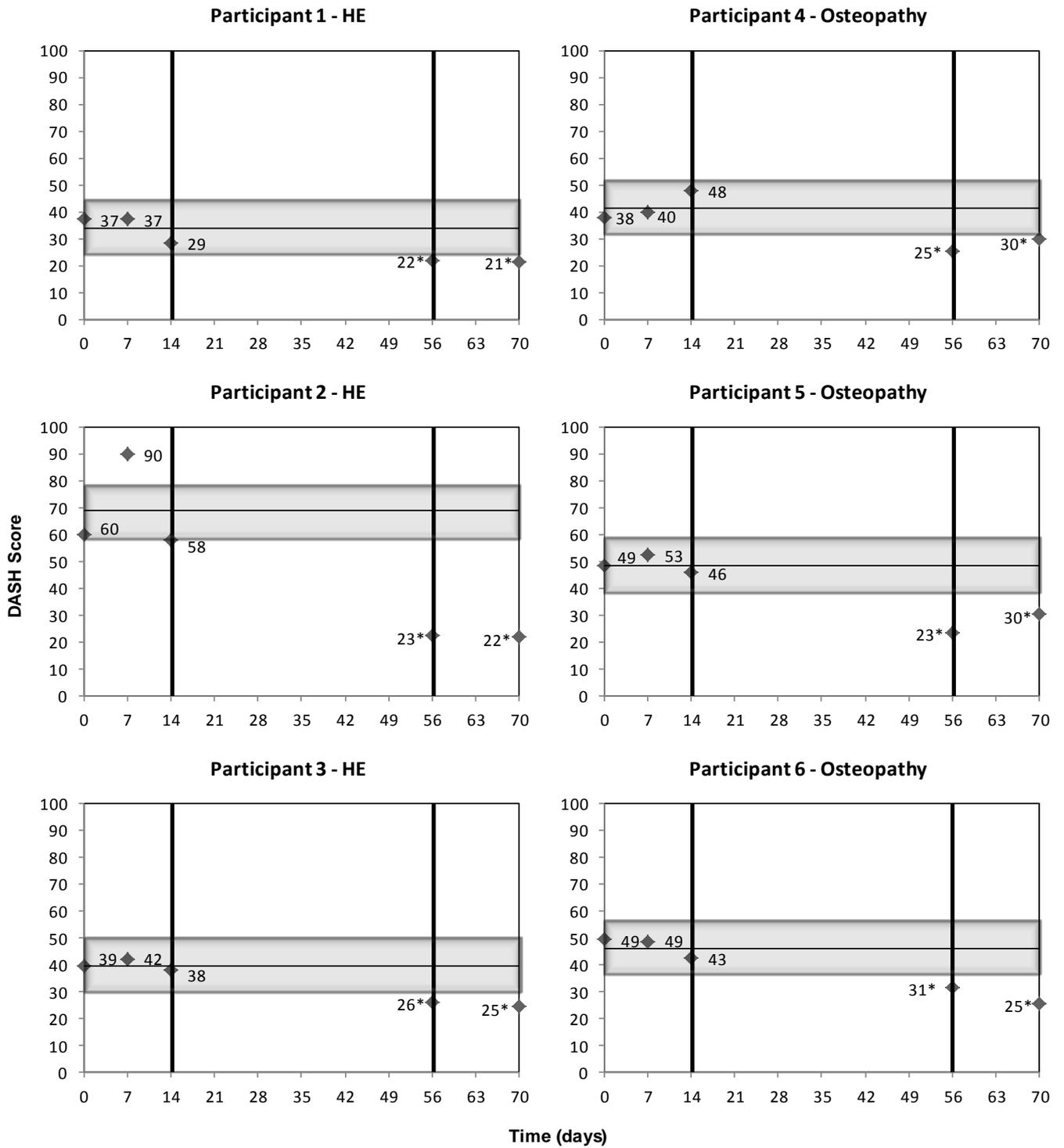


Figure 5. Profile of the DASH scores. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

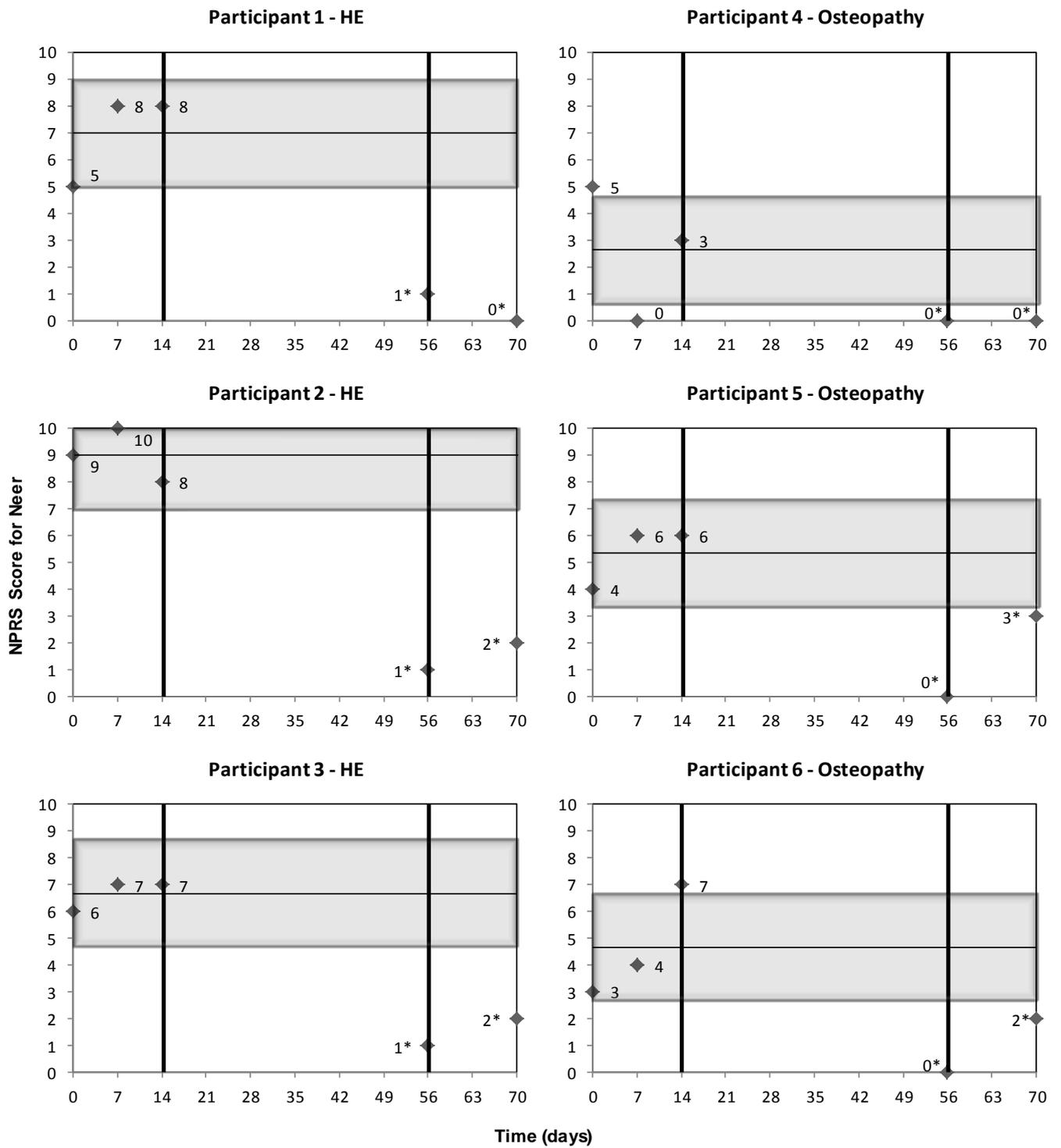


Figure 6. Profile of the NPRS scores during the Neer test. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

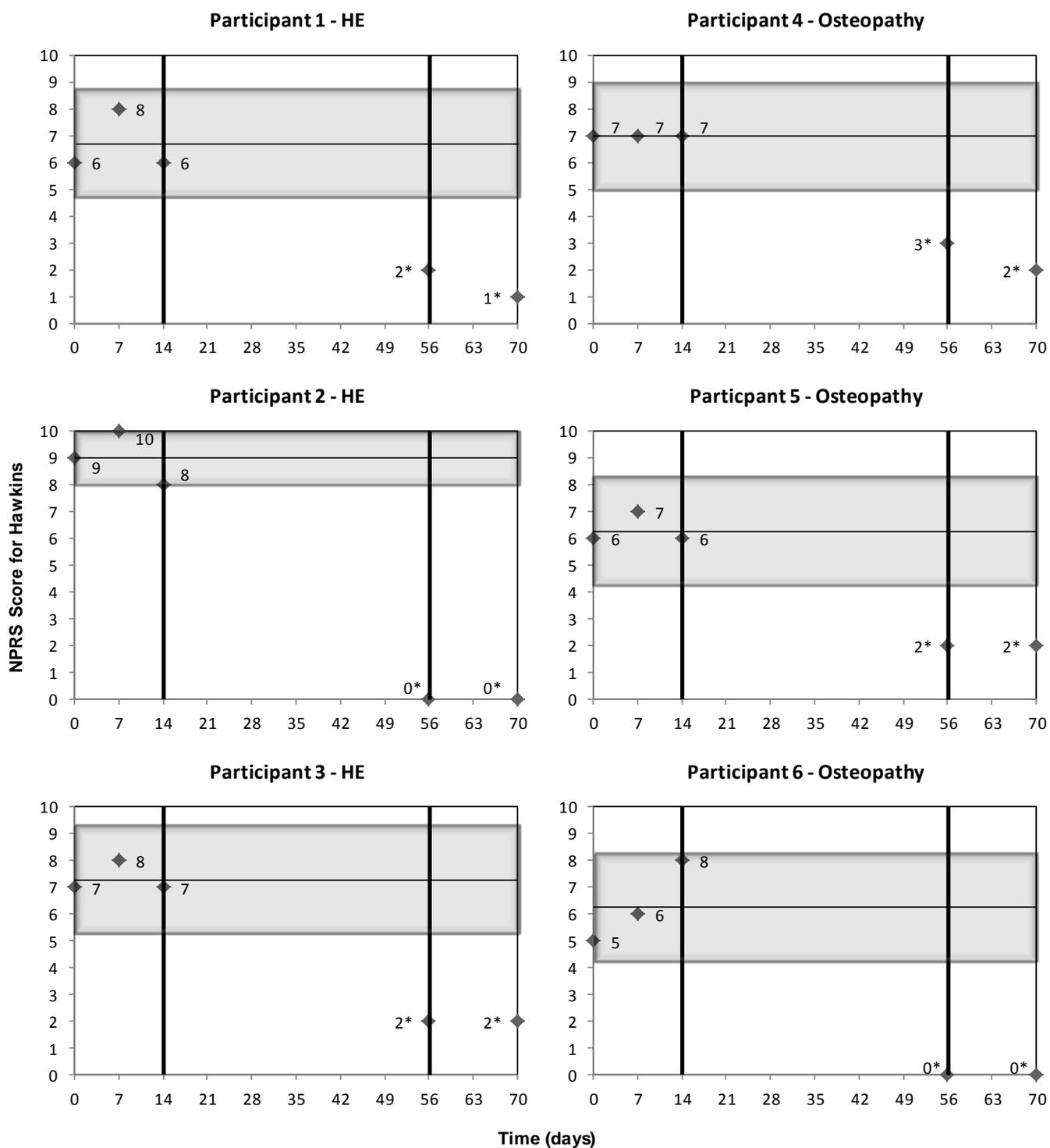


Figure 7. Profile of the NPRS scores during the Hawkins test. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

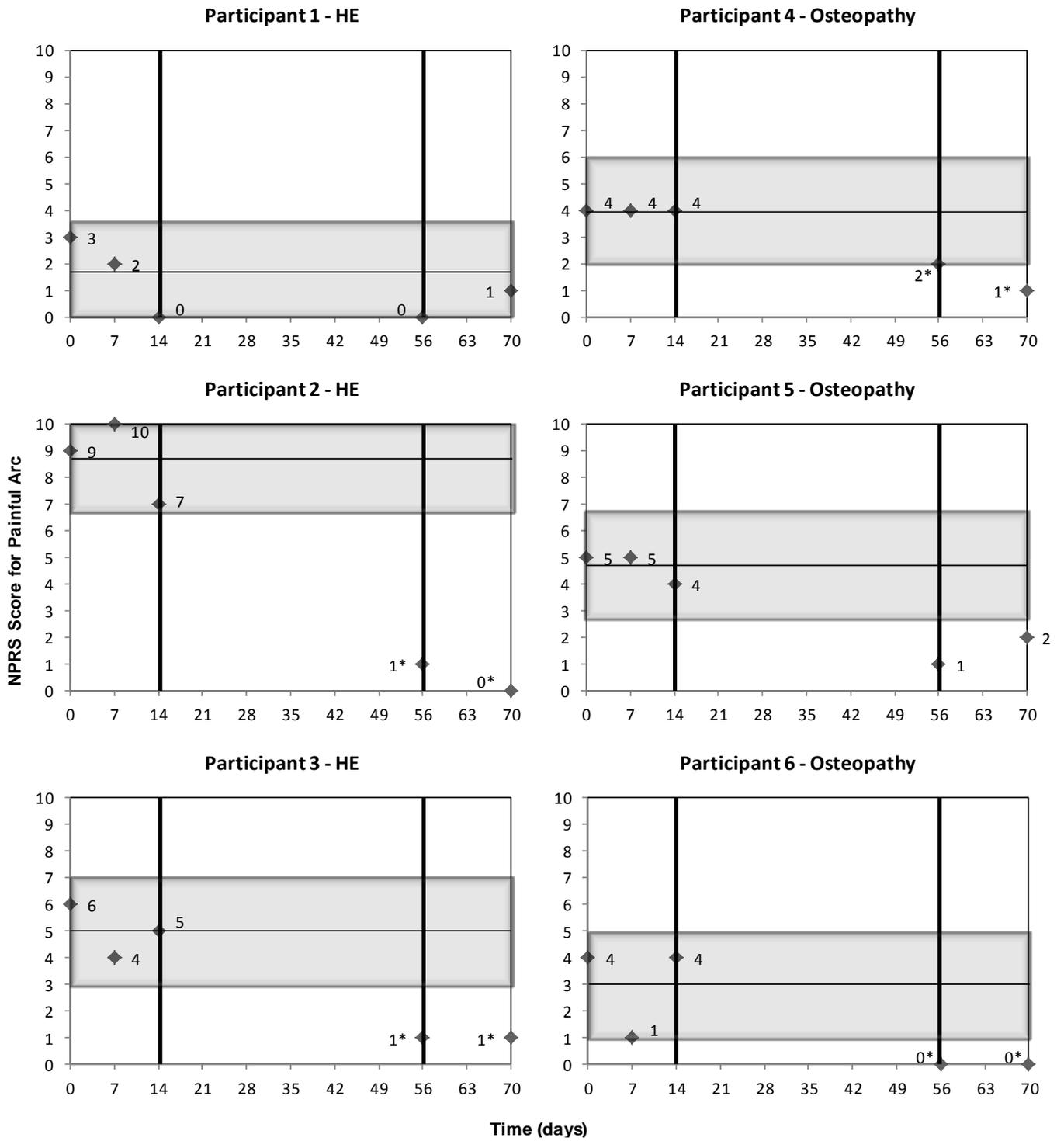


Figure 8. Profile of the NPRS scores during the painful arc test. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

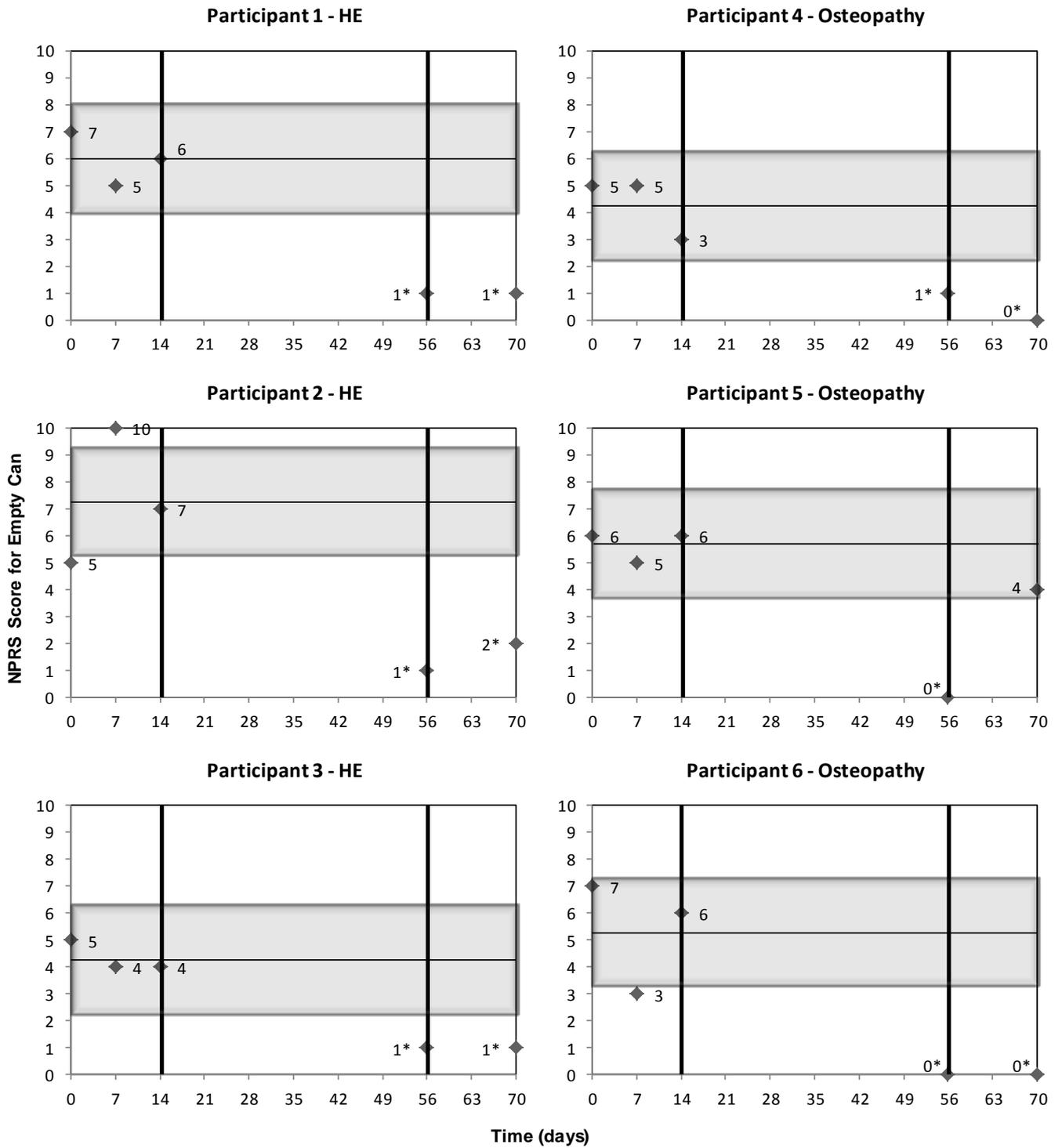


Figure 9. Profile of the NPRS scores during the empty can test. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

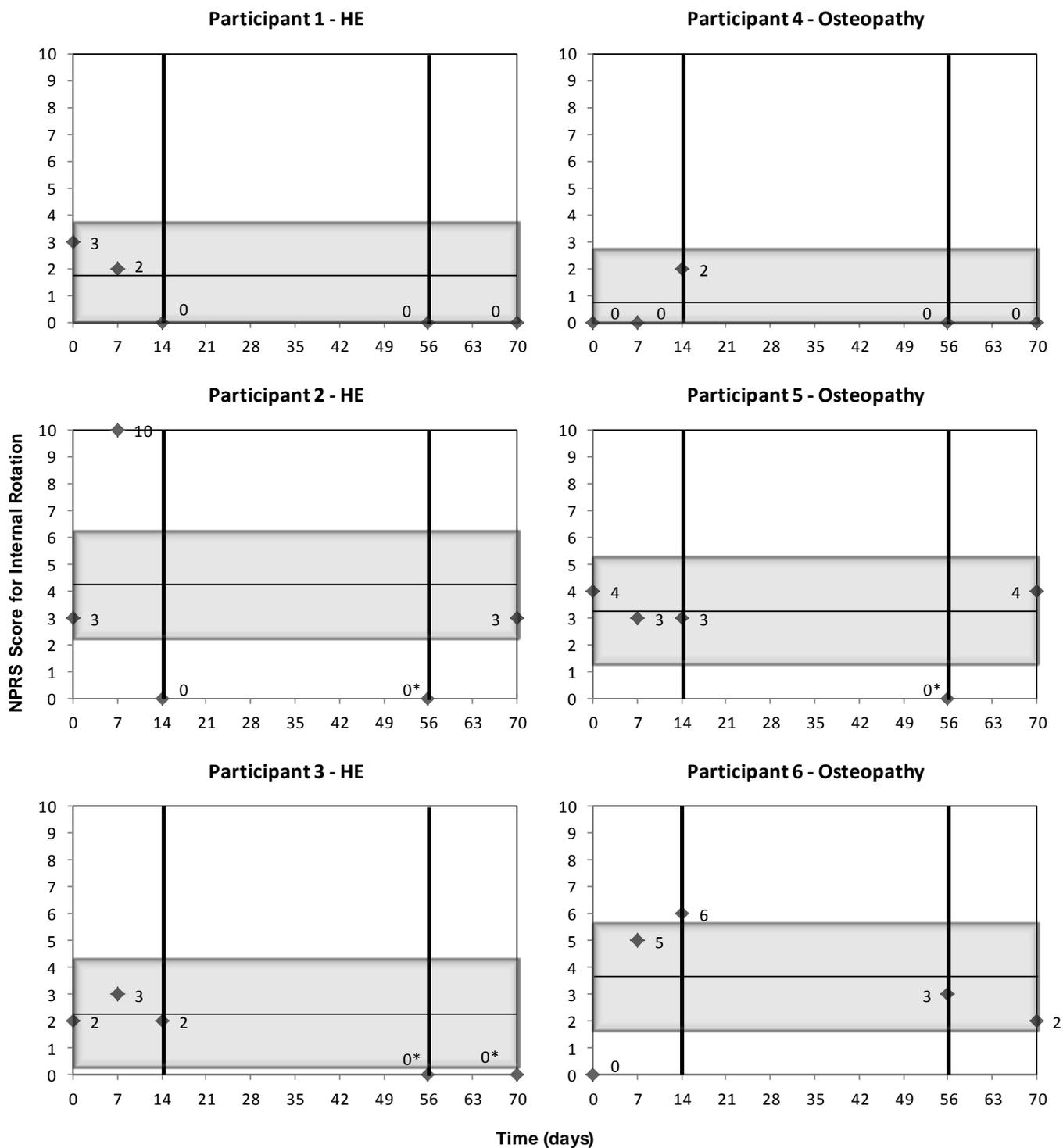


Figure 10. Profile of the NPRS during the active-resisted internal rotation test. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average.
 * = meaningful change. HE = Home-exercise.

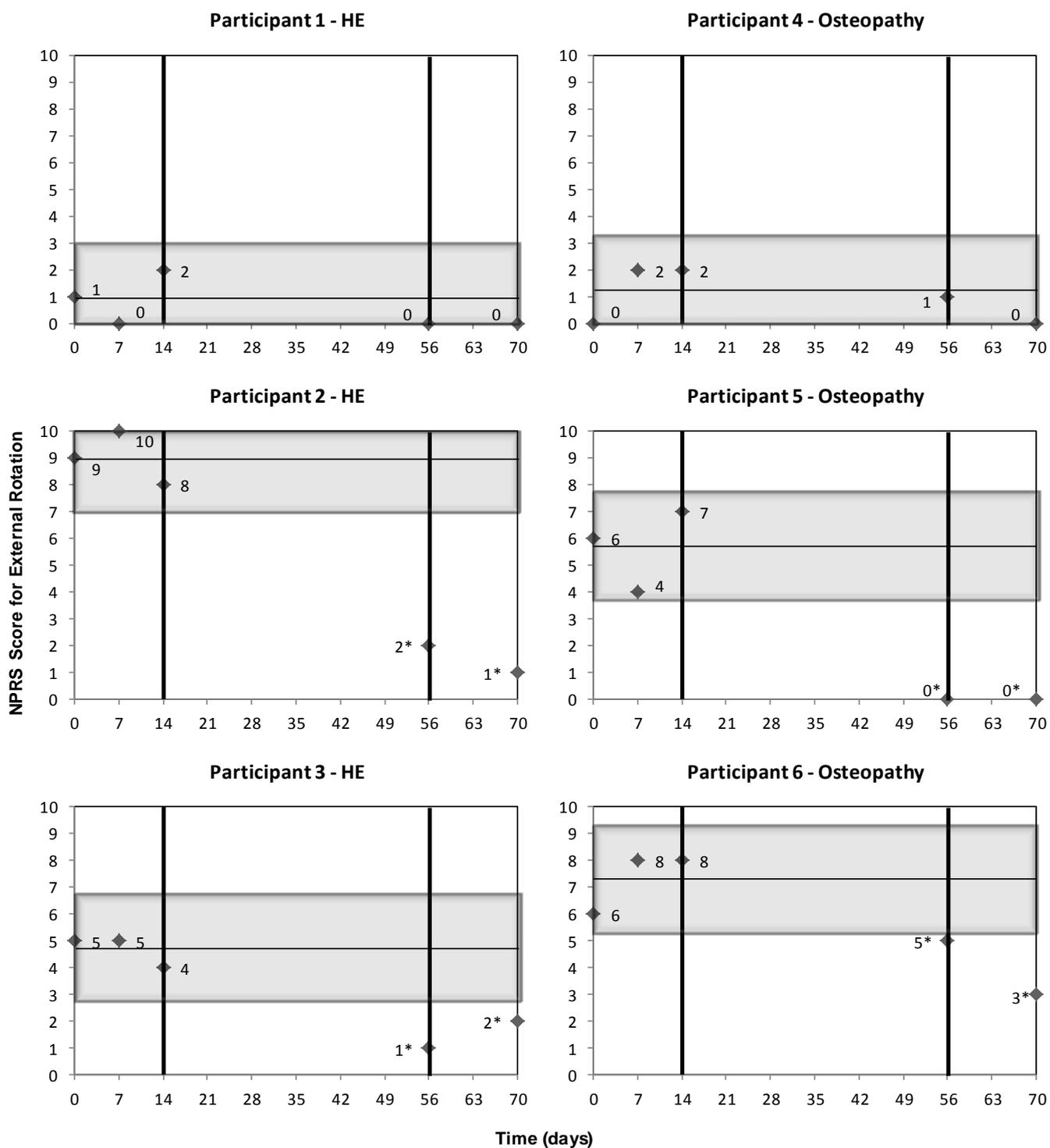


Figure 11. Profile of the NPRS during the active-resisted external rotation test. The two vertical lines represent the end of the baseline and intervention phases respectively. The grey band represents the baseline average \pm MCID with the horizontal line representing the baseline average. * = meaningful change. HE = Home-exercise.

9. Appendix of Manuscript

Interventions

Home-exercise Program



Sit down, with the upper arms close to the body and the elbows flexed at a right angle. Wrap the Thera-Band around both thighs and both wrists, as shown in the picture. Pull the shoulder blades back and push the sternum forward. Twist the forearms slightly outward. Hold the tension for 8-10 seconds. Repeat this exercise 10 times.



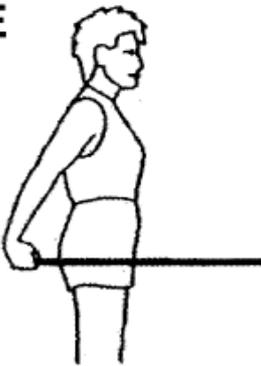
Sit on a stool or a therapeutic ball. Wrap the Thera-Band around both thighs. Extend both arms alongside the body, and pull the shoulder blades downward as you push your fingertips towards the ground. Keep arms straight and move them outward 10cm from the body. Hold the tension for 10 seconds. Repeat this exercise 10 times.



Sit down and place both elbows on the table. Grasp the Thera-Band with both hands, creating slight tension. Then stretch the Thera-Band apart without moving the elbows from the pad. Hold the tension for 10 seconds. Be careful to remain in an upright position during this exercise. Repeat this exercise 10 times.

D

Sit down or stand up. Grasp the Thera-Band at short length with both hands, creating a good tension. Then stretch the Thera-Band by pulling the shoulder blades together. Repeat the exercise 10 times.

E

Stand and take one end of the Thera-Band in each hand. Stretch arms downward and pull the Thera-Band backward with both hands, while moving the shoulder blades toward the spine. Push the sternum in a forward and upward direction. Hold the tension for 10 seconds. Repeat this exercise 10 times.

F

Sit down. Grasp the edge of the chair with one hand and lay the other arm over the head, placing the hand on the ear as shown in the picture. Flex the body in the same direction as the head to create a slight tension in the neck muscles. Hold the position for 15 seconds. Repeat this exercise twice on each side.

G

Place one hand on the table and hold a 1kg dumbbell in the other hand, as shown in the picture. Now swing the arm like a pendulum, approximately 10-20 cm in various directions. Continue this exercise for 3-5 minutes.

H



Stand. Squeeze a towel under the armpit. Take the wrist with the opposite hand, moving the arm across the front of the body and pulling it softly toward the ground. Hold the tension for 15 seconds. Repeat 3 times.

Osteopathic Treatment

Rhythmic techniques - includes kneading, stretching, articulation, inhibition, and traction. Rhythmic techniques involve repetitive movements to musculoskeletal structures (joints, muscles, tendons, ligaments, and fascia) in an attempt to re-establish movement, circulation and remove barriers that may be restricting joints (Hartman, 2001).

Muscle-energy technique - whereby the practitioner finds the initial “feather-edge” barrier to movement within a joint then asks the patient to apply a small force whilst the practitioner resists the movement. Muscle-energy technique is thought to improve range of motion in a joint, increase circulatory flow, decrease muscle tonicity, and to help strengthen weak muscles (Ward, 2003).

High-velocity-low-amplitude thrust (HVLA) – a short thrust applied at high velocity and low amplitude to a restricted joint in the spine or peripheral joint, including ribs. HVLA is used to improve range, quality and function of a restricted joint (Hartman, 2001).

Harmonic technique – rhythmic movement of a joint applied until a dynamic, harmonic rhythm is found. Harmonic technique is thought to improve quality of movement, relaxation of muscle, and improve fluid dynamics in the area (Hartman, 2001).

Activity modification – based on principles of active care (Liebenson, 1996) the practitioner gave advice on activity modifications for activities believed to be factors in the development and/or maintenance of shoulder impingement

Section 4: Appendices

Appendix A: Recruitment Poster and Flyer

Do you have shoulder pain?

If you are between the ages of 18-40 years and have recently developed pain in the shoulder then you may be eligible to participate in this study



I am currently completing a Master's of Osteopathy degree at Unitec New Zealand, part of which involves a research project. The study will investigate the effect of two rehabilitative programs on shoulder pain and disability.

Participants who take part in this study will receive a free 6 week rehabilitative program.

If you are interested or require more information please contact Tasman Darragh.

tazdarragh@gmail.com

027 665 8374



Can you help in this study?

Tasman Darragh
027 665 8374
Tazdarragh@gmail.com

Do you have shoulder pain?

If you are between the ages of 18-40 years and have recently developed pain in the shoulder then you may be eligible to participate in this study



I am currently completing a Master's of Osteopathy degree at Unitec New Zealand, part of which involves a research project. The study will investigate the effect of two rehabilitative programs on shoulder pain and disability.

Participants who take part in this study will receive a free 6 week rehabilitative program.

If you are interested or require more information please contact Tasman Darragh.
tazdarragh@gmail.com



Can you help in this study?

Appendix B: Editorial

Shoulder Pain?

Participate in research that could help you and others recover from common sport injuries

Every year over 200,000 kiwis join health and medical research studies to play their role in assisting the development of better treatments for many common conditions, including sports injuries.

Right now you are invited to participate in a free rehabilitation program if you live in Auckland, are aged between 18 and 40 years and have recently developed pain in your outer shoulder. This condition, usually termed “shoulder impingement syndrome”, is a common disorder that can cause pain and disability.

If you join the 6-week study, you’ll be helping yourself and others. You will learn a useful home exercise program that will take you 15 minutes a day, and if you are selected for Osteopathic treatment, this will be provided to you free of charge.

You will be assisting in a comparison of how a home-exercise program performs alone and when combined with an osteopathic treatment plan. If you participate in tennis, badminton, netball, basketball, squash, or any sport that involves raising your arms above your head, and experience outer shoulder pain, then you will likely learn some useful tips to share with teammates who will have also suffered from this condition.

For further information please go to www.shoulder.getparticipants.com

For further information please contact Tasman Darragh, 027 665 8374

Appendix C: Exercise Diary

Home-Exercise Program

Exercise Diary

Please record with a tick the exercises that were completed, and on which day, in the tables provided below.

Week One: _____ to _____

Exercises	A	B	C	D	E	F	G	H
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Your comments about the week:

.....

.....

.....

Feedback from supervised training session:

.....

.....

.....

Week Two: _____ to _____

Exercises	A	B	C	D	E	F	G	H
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Your comments about the week:

.....

.....

.....

Feedback from supervised training session:

.....

Week Three: _____ to _____

Exercises	A	B	C	D	E	F	G	H
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Your comments about the week:

.....

.....

.....

Feedback from supervised training session:

.....

.....

.....

Week Four: _____ to _____

Exercises	A	B	C	D	E	F	G	H
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Your comments about the week:

.....

.....

.....

Feedback from supervised training session:

.....

.....

.....

Week Five: _____ to _____

Exercises	A	B	C	D	E	F	G	H
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Your comments about the week:

.....

.....

.....

Feedback from supervised training session:

.....

.....

.....

Week Six: _____ to _____

Exercises	A	B	C	D	E	F	G	H
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Your comments about the week:

.....

.....

.....

Feedback from supervised training session:

.....

.....

.....

Appendix D: Ethics Approval

Tasman Darragh
27 Cambrai Avenue
Mt Roskill
Auckland

26 August 2010

Dear Tasman

Your file number for this application: 2010-1099

Title: *Comparison of a semi-standardised osteopathic treatment plan and a home-exercise program for the treatment of shoulder impingement syndrome*

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been **approved** for the following period:

Start date: 25 August 2010
Finish date: 24 August 2011

Please note that:

1. the above dates must be referred to on the information AND consent forms given to all participants
2. you must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC. We wish you every success with your project.

Yours sincerely

Lyndon Walker
Deputy Chair, UREC

CC: Rob Moran
Cynthia Almeida

Appendix E: Participant Information Sheet



RESEARCH INFORMATION FOR PARTICIPANTS

Comparison of a home-exercise program versus a home-exercise program combined with a semi-standardised osteopathic treatment plan for the treatment of shoulder impingement syndrome

You are invited to participate in our research investigation. Please read carefully through this information sheet before you make a decision about volunteering.

Principal Researcher

Tasman Darragh (Bachelor of Applied Science (Human Biology)) – Tasman is currently in his 1st year of the Masters of Osteopathy program at Unitec New Zealand.

Our Purpose

This study will look to measure the effect of osteopathic treatment when combined with a home-exercise program on pain and disability in people with shoulder impingement syndrome. Shoulder impingement is characterised by pain in the outer part of the shoulder and can reduce normal function of the affected shoulder.

The primary aim of this study is to see whether an osteopathic treatment plan can provide additional benefits when combined with an established and effective home-exercise program. By taking part in this study you are helping us discover if osteopathic treatment helps people who suffer from shoulder impingement syndrome. You are also helping us provide initial data for future osteopathic research.

Your voluntary participation

Your participation in this study is entirely voluntary and you may withdraw at any time during the study. Data collected from your involvement in the study may be withdrawn up until 1 week following your final assessment.

Who may participate?

We are looking for adults between the ages of 18-40 who suffer from shoulder impingement syndrome. Shoulder impingement syndrome is characterised by pain on the outer part of the shoulder that is usually made worse when performing tasks with the arm above shoulder level (an example would be hanging laundry or painting a wall). Participants may be included in the study if the pain has been present for less than 6 months. Unfortunately you will not be included in the study if:

- you have had significant injury or surgery on the affected shoulder within the past year
- you are currently receiving treatment on the affected shoulder (including pain relief medication)

Please feel free to contact the lead researcher if you are unsure about your eligibility.

What will happen in the study?

Should you agree to participate in the study, you will be required to attend 2 testing sessions which will include completing questionnaires related to your shoulder complaint and shoulder impingement tests. The study proper will commence 2 weeks after the initial session and will last for 6 weeks. You will be provided with a rehabilitative home-exercise program to perform regularly during this period. In this time you will be randomised to receive either 6 osteopathic treatments (1 per week) or 6 supervised training sessions (1 per week).

Home-exercise program

The home-exercise program will be run over a 6-week period. You will be asked to perform exercises for 15 minutes a day, 5 days per week over the 6-week period. The

exercises prescribed are based on scientific literature and have been found to be beneficial for reducing pain and disability for individuals with shoulder impingement syndrome.

Osteopathic treatment

If you are randomised to the Osteopathic treatment group you will receive 6 sessions over a 6-week period. The initial session will take 90 minutes, with subsequent sessions lasting 60 minutes. For effective osteopathic diagnosis you will be required to undress to your underwear (shorts are acceptable). Osteopathic techniques to be used are those that are regularly used in the Student Osteopathic Clinic. The osteopathic treatment will be carried out by a student osteopath currently completing their Masters of Osteopathy program at Unitec New Zealand, and will be supervised by a registered Osteopath.

Assessments

Two assessments are conducted throughout the course of the study, and will consist of questionnaires and shoulder impingement tests. Each questionnaire will take no more than 2-3 minutes each to complete.

The shoulder impingement tests include the Neer test, the Hawkins test, and the painful arc test. You will be required to rate the level of pain you experience when each test is performed. Each test will be performed by the principle researcher.

Shoulder impingement tests and questionnaires will take no longer than 15 minutes to complete.

What we do with the data and results, and how we protect your privacy.

Personal information is collected and stored under the guidelines provided by the Privacy Act 1993 and the Health Information Privacy Code 1994. Should you be randomised to the osteopathic treatment group, your name will be recorded on a case

history form as per usual clinical policy. However, in all other instances of information collection your identity will remain anonymous and you will simply have an identification number. If the information you provide is reported or published, this will be done in a way that does not identify you as its source. All the data recorded will be stored in a password-locked computer and archived in a locked file room in the Unitec Student Osteopathic Clinic and will be stored for a minimum of 5 years. Access to this data will be limited to the principle researcher (Tasman Darragh), the research supervisor, the osteopathic tutors at the Student Osteopathic Clinic, and yourself.

Discomforts/risks and benefits

The home-exercise program to be used in this study has been shown to reduce pain and disability in people who suffer from shoulder impingement syndrome. Likewise, manual therapy treatment (of which osteopathy shares similarities) has also been shown to be beneficial for people suffering from shoulder impingement syndrome.

There is a minimum of potential risks involved in this study. Mild stiffness and discomfort, nausea, fatigue, dizziness and ringing in the ears may be experienced following mobilisation of the cervical spine. The potential risk of stroke following this technique has been estimated in the literature at between 1 and 100,000 to 1 in 1 million treatments. All osteopathic techniques to be used will be discussed prior to being conducted and your consent will be sought. Should your symptoms worsen, you will be referred to an appropriate healthcare professional.

Compensation may be available in the unlikely event of injury of negligence

Should you incur a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act 2002. You may or may not be entitled to ACC compensation, depending on several factors such as whether or not you are an earner. ACC will usually cover a proportion of income lost due to a physical injury, this does not cover mental injury unless as a direct result from a physical injury. ACC cover may affect your right to sue. Please

contact your nearest ACC office for further information (0800 735 566) or visit their website: www.acc.co.nz

Please contact us if you need further information about the study.

Contact Details

Tasman Darragh

Phone: 027 6658374

Email: tazdarragh@gmail.com

Mr Jamie Mannion

Phone: 021 0629007

Email: jaymannion@gmail.com

UREC REGISTRATION NUMBER: (2010-1099)

This study has been approved by the UNITEC Research Ethics Committee from (date) to (date). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Appendix F: Consent Form

PARTICIPANT CONSENT FORM

Comparison of a home-exercise program versus a home-exercise program combined with a semi-standardised osteopathic treatment plan for the treatment of shoulder impingement syndrome

This form is to ensure that you understand the requirements of your participation and that you are aware of your rights. Please read carefully through the points below. If you are happy and agree with the points then please sign at the bottom of the page. If you have any questions at all please ask the researcher before signing this form.

- I have had the research project explained to me and I have read and understood the information sheet given to me.
- I understand that I don't have to be part of this if I don't want to and I may withdraw at any time prior to the completion of the research project.
- I understand that everything I say and the information I provide will be collected in accordance with the Health Information Privacy Code 1994 and kept confidential and in accordance with the Privacy Act 1993. I understand that the only persons who will have access to my information will be the researchers and relevant clinical staff.
- I understand that all the information I give will be stored securely on a computer at Unitec for a period of 5 years.

- I understand that my discussion with the researcher will be recorded on a case history form as per usual clinical policy.
- I understand that I can see the finished research document.
- I have had time to consider the information provided, to ask questions, and to seek any guidance.
- I give my consent to be a part of this project

Participant Signature: Date:

Principle Researcher: Date:

UREC REGISTRATION NUMBER: (2010-1099)

This study has been approved by the UNITEC Research Ethics Committee from (date) to (date). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Appendix G: *Manual Therapy* guide for authors

Manual Therapy

Guide for Authors

http://www.elsevier.com/wps/find/journaldescription.cws_home/623058/authorinstructions

The journal editors, Ann Moore and Gwen Jull, welcome the submission of papers for publication.

Submission to this journal proceeds totally online at <http://ees.elsevier.com/ymath>.

Use the following guidelines to prepare your article.

You will be guided stepwise through the creation and uploading of the various files.

The system automatically converts source files to a single Adobe Acrobat PDF version of the article, which is used in the peer-review process. Please note that even though manuscript source files are converted to PDF at submission for the review process, these source files are needed for further processing after acceptance. All correspondence, including notification of the Editor's decision and requests for revision, takes place by e-mail and via the Author's homepage, removing the need for a hard-copy paper trail.

The above represents a very brief outline of this form of submission. It can be advantageous to print this "Guide for Authors" section from the site for reference in the subsequent stages of article preparation.

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all Authors and tacitly or explicitly by the responsible

authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, without the written consent of the Publisher. Reliability Studies will only be accepted if they are innovative and add to the current body of knowledge within manual therapy.

Word Count

Manuscripts should not exceed the following word counts:

Original Research Articles using quantitative data - 3500 words

Original Research Articles using qualitative data - 4000 words

Reviews - 3500 words, but Systematic Reviews may be longer, up to 4000 words

Technical and measurement notes - 2000 words

Case reports and professional issues - 2000 words

Masterclass - 3500 words

Letters to the Editors - 500 words

These word counts do not include references or figures/tables

Presentation of Typescripts

Your article should be typed on one side of the paper, double spaced with a margin of at least 3cm. One copy of your typescript and illustrations should be submitted and authors should retain a file copy. Rejected articles will not be returned to the author except on request. Authors are requested to include line numbers to their manuscript in word prior to submission.

Authors are encouraged to submit electronic artwork files. Please refer to <http://www.elsevier.com/authors> for guidelines for the preparation of electronic artwork files. To facilitate anonymity, the author's names and any reference to their addresses should only appear on the title page. Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

Papers should be set out as follows, with each section beginning on a separate sheet:

title page, abstract, text, acknowledgments, references, tables, and captions to illustrations.

Title

The **title page** should give the following information:

- title of the article
- full name of each author
- you should give a maximum of four **degrees/qualifications** for each author and the current relevant appointment
- name and address of the department or institution to which the work should be attributed
- name, address, telephone and fax numbers, and e-mail address of the author responsible for correspondence and to whom requests for offprints should be sent.

Keywords

Include three or four keywords. The purpose of these is to increase the likely accessibility of your paper to potential readers searching the literature. Therefore, ensure keywords are descriptive of the study. Refer to a recognised thesaurus of keywords (e.g. CINAHL, MEDLINE) wherever possible.

Abstracts

This should consist of **250 words** summarising the content of the article. Abstracts should be used for Original Research, Professional Issues and Case Reports as well as for Technical and Measurement Notes papers.

Text

Headings should be appropriate to the nature of the paper. The use of headings enhances readability. Three categories of headings should be used:

- major ones should be typed in capital letter in the centre of the page and underlined
- secondary ones should be typed in lower case (with an initial capital letter) in the

left hand margin and underlined

- minor ones typed in lower case and italicised

Do not use 'he', 'his' etc. where the sex of the person is unknown; say 'the patient' etc.

Avoid inelegant alternatives such as 'he/she'. Avoid sexist language.

References

The accuracy of references is the responsibility of the author.

Text: In the text your reference should state the author's surname and the year of publication (Smith 1989). If there are two authors you should give both surnames (Smith & Black 1989). When a source has more than two authors, give the name of the first author followed by 'et al'.

Citations may be made directly (or parenthetically). Groups of references should be listed first chronologically, then alphabetically.

Examples:

"...sensitivity and variable specificity (Kerry and Rushton, 2003; Gross et al., 2005; Ritcher and Reinking, 2005)"

"Yaxley and Jull (1991) reported that no significant variation..."

List: References should be arranged first alphabetically and then sorted chronologically if necessary. Each reference to a paper needs to include the author's surname and initials, full title of the paper, full name of the journal, year of publication, volume and issue number and first and last page numbers. More than one reference from the same author(s) in the same year must be identified by the letters "a", "b", "c", etc., placed after the year of publication.

Examples:

Reference to a journal publication:

Lee M, Svensson NL. Effects of loading frequency on response of the spine to lumbar postero - anterior forces. *Journal of Manipulative and Physiological Therapeutics* 1993; 16(7): 439-466

References to a book should be in a slightly different format:

Kendall HO, Kendal FP, Boynton DA. *Posture and pain*. Baltimore: Williams and Wilkins; 1970. p. 135-8.

Reference to a chapter in an edited book:

Toupet M, Gage P, Heuschen S. Vestibular patients and aging subjects lost use of visual input and expend more energy in static postural control. In: Vellas B, Toupet M, Rubenstein L, et al., editors. *Balance and gait disorders in the elderly*. Paris: Elsevier; 1988. p. 183-98.

For more than 6 authors, the first three should be listed followed by 'et al.'

Citing and listing of Web references.

As a minimum, the full URL should be given. Any further information, if known (Author names, dates, reference to a source publication, etc.), should also be given. The date on which the website was last accessed should also be included. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list. When citing a Churchill Livingstone journal, the digital object identifier (DOI) may also be included, if noted, from the article's title page. Please note the following example: Joos U, Kleinheinz J 2000 Reconstruction of the severely resorbed (class VI) jaws: routing or exception? *Journal of Craniomaxillofacial Surgery* 28: 1-4. doi:10.1054/jcms.2000.0102 (last accessed 7 February 2006)

Figures and Illustrations

A detailed guide on electronic artwork is available on our website:

<http://www.elsevier.com/authors>

Tables

Number tables consecutively in accordance with their appearance in the text. Place footnotes to tables below the table body and indicate them with superscript lowercase letters. Avoid vertical rules. Be sparing in the use of tables and ensure that the data presented in tables do not duplicate results described elsewhere in the article. Ensure that each table is cited in the text.

Preparation of supplementary data. Elsevier now accepts electronic supplementary material (e-components) to support and enhance your scientific research.

Supplementary files offer the Author additional possibilities to publish supporting applications, movies, animation sequences, high-resolution images, background datasets, sound clips and more. Supplementary files supplied will be published online alongside the electronic version of your article in Elsevier Web products, including ScienceDirect: <http://www.sciencedirect.com>

In order to ensure that your submitted material is directly usable, please ensure that data is provided in one of our recommended file formats. Authors should submit the material in electronic format together with the article and supply a concise and descriptive caption for each file. For more detailed instructions please visit our artwork instruction pages at

<http://www.elsevier.com/wps/find/authors.authors/authorartworkinstructions>

Submitting Case Reports

The purpose of the Case Report is to describe in reasonable detail the application of manual therapy to a clinical use. Cases of particular interest are those of an unusual presentation, rare conditions or unexpected responses to treatment. The following points will assist authors in submitting material for consideration by the Editorial

Board:

- The Case Report should be between 1500 - 2000 words in length excluding references and illustrations. Longer studies will be considered by the Editorial Committee if of an exceptional quality.
- An abstract is required and the introductory paragraph should provide the reader with an overview of the study in general.
- The method of presentation to the treating practitioner should be detailed along with the symptoms and their behaviour. A body chart illustrating the symptoms is considered essential.
- The history (present and past) should be reported. Relevant work and leisure activities should also be presented in this section.
- The objective examination findings should be detailed in a concise manner.
- Treatment of the condition should be reported along with results. It is essential to clearly state what was done to achieve the reported results.
- The management of the condition should then be discussed with references to the literature to support what was done. Authors should remember it is a reasoned article rather than a purely factual report.
- The Case Report should conclude with a brief summary.
- Case Reports should be submitted online at <http://ees.elsevier.com/ymath>

For further details on the Case Report section please contact: Jeffrey D. Boyling, Jeffrey Boyling Associates, Broadway Chambers, Hammersmith Broadway, LONDON, W6 7AF, UK. Tel: +44 (0) 7814 880 370 E-mail: jeffboyling@yahoo.co.uk

Submitting a Masterclass

The purpose of the Masterclass section is to describe in detail clinical aspects of manual therapy. This may relate to specific treatment techniques, a particular management approach or management of a specific clinical entity.

- The article should be between 3500 - 4000 words in length excluding references.
- A short summary should precede the main body of the article overviewing the

contents.

- The introduction should review the relevant literature and put the subject matter into context.
- The main body of the text will describe the technique or approach in detail.
- Clinical indications and contraindications should be outlined when relevant.
- Illustrations are considered an essential part of the Masterclass in order to fully inform the reader and a minimum of six photographs or line drawings are required.

In addition, authors may wish to include supplementary material which would be available online only. This may include, for example, podcasts, videoclips, animation sequences, high-resolution colour images, author reflections on the masterclass, and background datasets - please visit the Guide for Authors for further details at www.elsevier.com/math.

For further details and full instructions for authors for the Masterclass section please contact: Karen Beeton, Department of Physiotherapy, University of Hertfordshire, College Lane, HATFIELD, Herts, AL10 9AB, UK. Tel: +44 (0)1707 284114 Fax: +44 (0)1707 284977 E-mail: k.s.beeton@herts.ac.uk

Submitting a Professional Issue

The purpose of a Professional Issue is to raise an issue of professional importance that affects the national or international community. The issue may concern audits, continuing professional development, data collection methods, education, innovation in practice, professional practice, research goals, service delivery or treatment protocols around the globe. It should provide a solid foundation for the development of better patient outcomes whilst improving the quality of professional practice. The following points will assist authors in submitting material for consideration by the Editorial Board:

- The Professional Issue should be no more than 2000 words in length excluding

references and illustrations. Longer studies will be considered by the Editorial Board if of an exceptional quality.

- An abstract is required.
- The introductory paragraph should provide the reader with an overview of the issue in general.
- The main body of the text will set out the issue in a reasoned manner.
- The Professional Issue should conclude with a brief summary and the implication to the professional practice of manual therapy.
- Professional Issues should be submitted online at <http://ees.elsevier.com/ymath>

For further details on the Professional Issue section please contact: Jeffrey D. Boyling, Jeffrey Boyling Associates, Broadway Chambers, Hammersmith Broadway, LONDON, W6 7AF, UK. Tel: +44 (0) 7814 880 370. E-mail: jeffboyling@yahoo.co.uk

Copyright Information

A "Transfer of Copyright" agreement will be sent to authors following acceptance of a paper for publication. A paper is accepted for publication on the understanding that it has not been submitted simultaneously to another journal in the English language. All authors must sign the "Transfer of Copyright" agreement before the article can be published. This transfer agreement enables Elsevier Science Ltd to protect the copyrighted material for the authors, without the author relinquishing his/her proprietary rights. The copyright transfer covers the exclusive rights to reproduce and distribute the article, including reprints, photographic reproductions, microfilm or any other reproductions of a similar nature, and translations. It also includes the right to adapt the article for use in conjunction with computer systems and programs, including reproduction or publication in machine-readable form and incorporation in retrieval systems. Authors are responsible for obtaining from the copyright holder permission to reproduce any material for which copyright already exists.

Funding body agreements and policies

Elsevier has established agreements and developed policies to allow authors whose articles appear in journals published by Elsevier, to comply with potential manuscript archiving requirements as specified as conditions of their grant awards. To learn more about existing agreements and policies please visit <http://www.elsevier.com/fundingbodies>

Patient Anonymity

Studies on patients or volunteers require ethics committee approval and informed consent which should be documented in your paper. Patients have a right to privacy. Therefore identifying information, including patients' images, names, initials, or hospital numbers, should not be included in videos, recordings, written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and you have obtained written informed consent for publication in print and electronic form from the patient (or parent, guardian or next of kin where applicable). If such consent is made subject to any conditions, Elsevier must be made aware of all such conditions. Written consents must be provided to Elsevier on request. Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note. If such consent has not been obtained, personal details of patients included in any part of the paper and in any supplementary materials (including all illustrations and videos) must be removed before submission

English Language Service

Please write your text in good English. Authors who require information about language editing and copyediting services pre- and post-submission please visit <http://www.elsevier.com/languagepolishing> or our customer support site at <http://epsupport.elsevier.com> for more information. Please note Elsevier neither endorses nor takes responsibility for any products, goods or services offered by

outside vendors through our services or in any advertising. For more information please refer to our Terms & Conditions: <http://www.elsevier.com/termsandconditions>

Permissions Information

Written permission to produce borrowed materials (quotations in excess of 100 words, illustrations and tables) must be obtained from the original copyright holders and the author(s), and submitted with the manuscript. Borrowed materials should be acknowledged in the captions as follows: 'Reproduced by kind permission of (publishers) from (reference)'.

Page Proofs

When your manuscript is received by the Publisher it is considered to be in its final form. Proofs are not to be regarded as "drafts".

One set of page proofs in PDF format will be sent by e-mail to the corresponding Author, to be checked for typesetting/editing. No changes in, or additions to, the accepted (and subsequently edited) manuscript will be allowed at this stage. Proofreading is solely your responsibility.

A form with queries from the copyeditor may accompany your proofs. Please answer all queries and make any corrections or additions required. The Publisher reserves the right to proceed with publication if corrections are not communicated. Return corrections within 48 hours of receipt of the proofs. Should there be no corrections, please confirm this.

Elsevier will do everything possible to get your article corrected and published as quickly and accurately as possible. In order to do this we need your help. When you receive the (PDF) proof of your article for correction, it is important to ensure that all of your corrections are sent back to us in one communication. Subsequent corrections will not be possible, so please ensure your first sending is complete. Note that this

does not mean you have any less time to make your corrections, just that only one set of corrections will be accepted.

Author Enquiries

For enquiries relating to the submission of articles (including electronic submission where available) please visit <http://www.elsevier.com/authors> There is also the facility to track accepted articles and set up e-mail alerts to inform you of when an article's status has changed, as well as detailed artwork guidelines, copyright information, frequently asked questions and more at: <http://authors.elsevier.com/TrackPaper.html>. Contact details for questions arising after acceptance of an article, especially those relating to proofs, are provided when an article is accepted for publication.

Changes to authorship

This policy concerns the addition, deletion, or rearrangement of author names in the authorship of accepted manuscripts:

Before the accepted manuscript is published in an online issue: Requests to add or remove an author, or to rearrange the author names, must be sent to the Journal Manager from the corresponding author of the accepted manuscript and must include: (a) the reason the name should be added or removed, or the author names rearranged and (b) written confirmation (e-mail, fax, letter) from all authors that they agree with the addition, removal or rearrangement. In the case of addition or removal of authors, this includes confirmation from the author being added or removed. Requests that are not sent by the corresponding author will be forwarded by the Journal Manager to the corresponding author, who must follow the procedure as described above. Note that: (1) Journal Managers will inform the Journal Editors of any such requests and (2) publication of the accepted manuscript in an online issue is suspended until authorship has been agreed.

After the accepted manuscript is published in an online issue: Any requests to add,

delete, or rearrange author names in an article published in an online issue will follow the same policies as noted above and result in a corrigendum.

Checklist

Before submitting your paper, please check that:

- All files are uploaded.
- The reference list is complete and in correct style.
- Written permission from original publishers and authors to reproduce any borrowed material has been obtained.

© Copyright 2012 Elsevier | <http://www.elsevier.com>