Is soft tissue massage an effective treatment for mechanical shoulder pain? A study protocol

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Very little research has been conducted into the effectiveness of soft tissue massage as an intervention for the treatment of mechanical shoulder pain. Studies that have been conducted suffer from methodological issues, poor long-term follow-up and have conflicting results. The aim of this study, therefore, is to provide treating clinicians with improved evidence regarding the effectiveness of soft tissue massage for shoulder pain of local mechanical origin. Participants referred to the trial with mechanical shoulder pain will be assessed for range of motion, functional ability, and pain by a blinded assessor. Participants will then be randomly allocated to either an exercise-only group or an exercise and soft tissue massage group. Both groups will receive seven treatment sessions from a physical therapist over a period of 4 weeks. One week after the cessation of treatment, all participants will be reassessed by the same blinded assessor. Three months after cessation of treatment, subjects will again be reassessed. The primary outcome will be pain measured on a visual analogue scale (VAS) 1 week following the cessation of treatment. Secondary analyses will be pain at 3 months, the descriptive and present pain index sections of the short form McGill pain questionnaire, patient specific functional scale, and percentage improvement in pain scores and range of motion at 1 week following the cessation of treatment and at 3 month follow-up. Analysis of data will be carried out by a statistician who is blinded to group membership. Primary analyses will be by intention-to-treat.

Keywords: Clinical trial, Function, Massage, Pain, Shoulder

Shoulder pain is an important medical and socio-economic problem in the Western world with between 7 and 26% of the population reporting shoulder problems at any one time.¹ The presence of pain and stiffness in the shoulder can lead to an inability to work and/or to carry out domestic and recreational activities, thus creating a high burden of disease for both the individual and society. For many people, shoulder complaints are not self-limiting: almost 40% of patients who visited a general practitioner for shoulder pain reported complaints that had persisted for more than 12 months.²

Up to 50% of patients who have been diagnosed with shoulder pain are referred to a physical therapist for treatment.³ Despite this, there is little evidence of effectiveness for many of the common physical therapy treatments that are currently in use.⁴

Trigger points and tender, taut bands in muscles have been associated with shoulder problems since the time of Hippocrates.⁵ Trigger points are

characterized by local tenderness on palpation and pain on contraction of the muscle.⁵ Inter-rater reliability for identification of trigger points and taut bands around the shoulder has been shown to have moderately high reliability (percentage of pairwise agreement $\geq 70\%$; range: 63–93%).⁶ Common sites for trigger points around the shoulder include all muscles of the rotator cuff, latissimus dorsi, teres major, deltoid and the pectoral muscles.^{5,7} Treatment of these tender areas by soft tissue massage has been theorized to improve the viscoelastic properties of the muscle and thus, in turn, improve the biomechanics of shoulder motion, resulting in less pain and improved function.^{8,9}

Soft tissue massage techniques have been shown to be extensively used in physical therapy practice for the treatment of shoulder pain.¹⁰ Despite this, there is very limited evidence demonstrating its efficacy as a treatment modality. A course of specific soft tissue massage to the muscles around the shoulder over a 2 week period has been shown to provide improvements in abduction (mean: 42.2°, 95% CI: 24.1–60.4°), flexion (mean: 22.6°, 95% CI: 12.4–32.6°),

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hand behind back reach (mean: 11.0 cm further), reported function [mean improvement of 8.6 points out of 30 on the patient specific functional scale (PSFS),¹¹ 95% CI: 4.9–12.3 points] and reported pain [mean: 26.5 mm improvement on visual analogue scale (VAS), 95% CI: 5.3–47.6 mm] in patients with mechanical shoulder pain compared with no treatment.¹² This study, however, lacked any longer-term measurement effect and also did not compare against either a placebo or other treatment. Similarly, Godges *et al.*¹³ demonstrated that, in a group of patients with limited glenohumeral external rotation and overhead reach, one treatment of soft tissue massage combined with proprioceptive neuromuscular facilitation resulted in moderate improvements in both flexion (mean: 9.6 cm, 95% CI: 5.2–14.0 cm) and external range of motion (mean: 16.4°, 95% CI: 12.5–20.3°). In contrast, however, Senbursa *et al.*¹⁴ was unable to demonstrate improvements in pain or range of motion in patients with impingement syndrome treated with a combination of soft tissue massage, joint mobilizations, ice, stretching, and strengthening exercises compared with stretching and strengthening exercises alone. Therefore, there is some conflict within the evidence regarding the effectiveness of soft tissue massage in the treatment of shoulder pain.

The proposed study is aimed at providing clinicians with improved evidence concerning the efficacy of shoulder massage to treat shoulder pain. Specifically, we will investigate whether the addition of soft tissue massage to a commonly used treatment, a rotator cuff exercise programme aimed at improving strength, range of motion, and motor control provides additional benefit over the rotator cuff exercise programme alone.

Methods

All patients with shoulder pain referred to the physical therapy department during the trial period will be given an information sheet about the trial by a physical therapist (Fig. 1). Those patients who are interested in participating in the trial will be invited to discuss the aims and procedures of the trial with one of the investigators. Ethical approval for this study has been received from the University of Sydney, Sydney South West and Sydney South East Illawarra Area Health Services. Written consent will be obtained from all participants before entry to the study.

Demographic information including age, gender, and duration of symptoms will be collected on all patients who are deemed eligible for the trial. All participants will undertake an initial interview by a physical therapist to determine eligibility for the trial which will consist of a standardized musculoskeletal assessment of the upper quadrant and cervical spine.¹⁵ To be *included*, participants must be:

- aged between 18 and 80 years;
- referred to physical therapy for management of shoulder pain;
- able to understand spoken English.

Participants will be *excluded* if they report any of the following:

- shoulder pain due to trauma in the previous 4 weeks;
- shoulder pain reproduced with any neck movement;
- shoulder pain due to serious pathology (e.g. neoplasm, acute inflammatory condition, recent/un-united fracture);
- worker's compensation claim relating to the shoulder pain.

These will be confirmed by taking a thorough history and physical examination, and imaging as relevant.

Interventions

Exercise

It is envisaged that participants entering into this study will have varying degrees of shoulder pain and disability. To allow for this, the treating therapist will be provided with a range of exercises to improve range of motion, strength and motor control from which they can select appropriate exercises specific to the individual participant. Therapists can progress these as necessary according to their clinical judgment. All study participants will receive exercise compliance diaries in which they will record the exercises undertaken in each session. The level and intensity of exercises will be determined by the treating physical therapist and will be updated as required at each treatment session. The treating physical therapist will demonstrate the exercises to the participant and then monitor performance while the participant practices the exercises and provides feedback as necessary.¹⁶

Soft tissue massage

Each of the study participants who are allocated to the massage plus exercise group will receive 10–15 min of soft tissue massage in addition to the exercises. Massage will be applied to the following areas:

1. lateral border of the scapula in full shoulder flexion;
2. posterior deltoids region at the end of range of horizontal flexion;
3. pectoralis major in the pectoralis major stretch position;
4. anterior deltoids region at the end of range of hand behind back.

The soft tissue massage will be applied with the therapist's fingertips using massage cream and applied in the longitudinal direction along the length of the muscle. Therapists will be instructed that the massage should be at an intensity where it may produce some discomfort but this should not extend past the cessation of the massage. Therapists may feel tight areas of muscle during palpation which may indicate areas that they may need to concentrate the soft tissue massage on. During the soft tissue massage, therapists may increase the range of motion

Figure 1 Diagram showing the flow of participants through each stage of the study. F = flexion range of motion; Abd = abduction range of motion; HBB = hand behind back range of motion; Q = question.

that the shoulder is held in a passive resistance to the movement and pain experienced by the patient decreases. This approach is similar to that used by van den Dolder and Roberts,¹² which resulted in significant and immediate improvements in range of motion, pain, and reported function against a no treatment group. The aim of this massage is to relax muscles and the release bonds between fascia,

integument, and muscles to eliminate pain, increase range of motion and thus the patient's function. All treating therapists will be trained by one of the researchers in the correct application of the soft tissue massage technique.

All treating physical therapists will have several years of experience in the treatment of musculoskeletal conditions, including shoulders. For the study,

the treating therapists will be intensively trained by one of the researchers in the application of both the exercise regimens and the soft tissue massage techniques.

Outcome assessments

A blinded assessor, previously trained in the use of the assessment instruments, will make all outcome measurements. Each outcome will be measured at three time points: before randomization, 5 weeks after commencement of treatment, and 3 months after cessation of treatment. Outcomes will include measures in the following domains:

- *pain* using the short form McGill pain questionnaire (SFMPQ). The SFMPQ consists of a 100 mm VAS, a descriptive pain scale consisting of 15 words commonly used to describe pain with each word rated on a four-point scale, and a present pain index (PPI) on which the patient is asked to mark their current level of pain on a 1–5 Likert scale. The SFMPQ has been shown to correlate well with the long version of the McGill pain questionnaire with Pearson's r between 0.64 and 0.87;¹⁷
- *reported function* using the PSFS questionnaire. The PSFS requires participants to choose three activities that they have difficulty performing due to shoulder pain, and to rate the level of difficulty for each activity on an 11-point scale (0–10). The test–retest reliability and sensitivity to change for the PSFS have been shown to be excellent: intraclass correlation coefficient (type 2,1) $R = 0.84$ and Pearson's $r = 0.78$, respectively;¹⁸
- *reported disability* using the shoulder pain and disability index (SPADI) questionnaire. The SPADI is a shoulder-specific self-administered questionnaire consisting of 13 items divided into pain and disability subscales which are scored on an 11-point scale (0–10). The SPADI has been shown to correlate well with other health status measures with correlation between the SPADI and the sickness impact profile of between $r = 0.01$ and $r = 0.57$;¹⁹
- *range of motion*. Three directions of shoulder movement will be measured, flexion, abduction, and internal rotation (hand behind back). Flexion and abduction will be measured using photography, and hand behind back using a tape measure. For flexion and extension, markers will be placed on the tip of the acromion, the lateral angle of the twelfth rib, the lateral epicondyle of the elbow, and the spinous processes of T1 and T7. Participants will be instructed to flex, and then abduct the arm as far as possible with the thumb pointing up, and a photograph will be taken at the end of each movement. On the photographs, the markers will be joined by lines at the end of range of each movement, and the resultant angles will be measured using a protractor. The flexion angle will be calculated as the angle formed by the bisection of the lines drawn between the tip of the acromion and lateral epicondyle of the elbow, and the tip of the acromion and rib angle. Abduction range will be calculated as the angle formed by the bisection of two lines between the T1 and T7 spinous processes, and between the tip of the acromion and lateral epicondyle of the elbow. Both abduction and flexion measurements have been shown to have high test–retest reliability, with intraclass correlation coefficients (type 2,1) of 0.90 and 0.88, respectively.²⁰ Hand

Figure 2 Measurement of hand behind back using tape measure to measure distance from PSIS level to tip of thumb.

behind back will be measured as the distance from the mid-line between the posterior superior iliac spines (PSIS) to the tip of the thumb and recorded in centimetres above the PSIS (a positive measure) or below the PSIS (a negative measure),²¹ as shown in Fig. 2.

Two additional outcomes will be measured 1 week after the sixth treatment, and 3 months following cessation of treatment. These measures are:

- global pain improvement, measured as the percentage improvement in pain. Participants rate their global change in pain compared with their pain at initial assessment reported as a percentage;²²
- compliance with the prescribed exercise programme will be reported in a diary using a four-point Likert scale labelled with the following four responses: all of the time, most of the time, some of the time, or none of the time.

For all questionnaire assessments, participants will show their previous responses before completing each again, except at the initial assessment, as this has been shown to improve the reliability of responses.²³

The primary outcome for the study will be the VAS measure of the SFMPQ at 1 week following the cessation of treatment. Secondary outcomes for the study will be changes between groups in the descriptive and PPI sections of the SFMPQ, PSFS, percentage improvement in pain scores, and range of motion at 1 week following the cessation of treatment and 3 month follow-up.

Random allocation

Subjects will be randomly assigned to one of two groups by a computer-generated schedule. The allocation schedule will be prepared off-site by one of the investigators not otherwise involved in the recruitment process and provided in opaque sequentially numbered envelopes, which will be opened by the treating physical therapist to ensure that the assessor remains blinded to group allocation of participants.

Power calculations

Sample size was calculated based on a predetermined difference in change scores of 10 mm on the VAS of the SFMPQ between the experimental and control groups. This difference was based on what was believed to be a clinically worthwhile effect, and also on the results of our preliminary study into the effectiveness of soft tissue massage for shoulder pain.¹² Sample size calculations, assuming a standard deviation of 15 mm on the VAS and a dropout rate of 10%, indicated the need for 40 participants in each group (80 participants in total).

Analysis of data

All data analysis will be conducted on an intention-to-treat basis using all randomized participants by a statistician blinded to group membership. Demographic characteristics and baseline data will be summarized using descriptive statistics. In order to estimate treatment efficacy, between-group mean change scores (95% confidence intervals) will be compared using analysis of variance tests for all outcome measures.

Discussion

Shoulder pain is a commonly occurring and potentially debilitating condition that affects many people. This planned study will use a single-blinded randomized controlled design to investigate whether the addition of soft tissue massage to exercise therapy in the treatment of shoulder pain has greater effects on pain, disability, and function over exercise therapy alone. The benefits of soft tissue massage as a commonly used treatment technique in the treatment of shoulder pain are not well established and this study will assist therapists to decide whether massage should be added to exercise regimens.

The study design of having two active treatment groups will ensure that any effects of the personality of each therapist and the treatment environment are equally distributed between participants. A number of treating therapists will be included to increase the external validity of the results. As there is no 'gold standard' therapeutic exercise regimen for the treatment of shoulder pain, we chose to employ a pragmatic design that allows the therapists to choose from a range of shoulder exercises based on their own clinical reasoning and experience. The soft tissue massage employed in this study has been shown to have an immediate effect on patient pain, range of motion, and disability,¹² but has not been compared to an active treatment or subjected to longer term follow-up.

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