Project Title: Exercise intervention for subacromial impingement syndrome. A randomised controlled trial of two rehabilitation protocols.

Design:

The study will be a prospective, parallel-groups trial with two intervention arms. Volunteers with shoulder pain will be randomly allocated to either Intervention A or Intervention B. The trial will use concealed allocation, blinded outcome measurements, with a blinded data analyst using the intention to treat principle.

Inclusion criteria

Volunteers will recruited from patients referred for physiotherapy treatment by General and Specialist Physicians from within the service area of Fairfield Hospital. Subjects will be:

a. Aged between 30 and 65 years with unilateral shoulder pain.

With the following features:

a. Pain is intermittent.
b. Pain behaves mechanically (pain is aggravated by movement and reduces with rest).
c. Positive impingement signs (positive Hawkins-Kennedy, positive and Neer's test, positive painful arc, positive Allingham's test).

Exclusion criteria

Subjects would be excluded if they present with any of the following:

a. Suspected or diagnosed pathologies arising from vertebral column structures.
b. Diagnoses of neoplastic disorders.
c. Pain potentially from inflammatory (including adhesive capsulitis) or neurogenic origin.
d. Clinical features (Murrell and Walton 2001) or radiological evidence of rotator cuff tear.
e. Shoulder trauma, or cervical or upper thoracic spine injury in the previous 12 weeks.
f. Previous shoulder dislocation.
g. Previous CVA.
h. Severe pain that prevents exercises from being undertaken.
i. Bilateral shoulder pain (since comparison with the contralateral side is required for certain outcome measurements).
j. Inability to provide informed consent.
k. Patients who decline to comply with an exercise program.
l. Patients who do not speak English, Vietnamese or Arabic.

Recruitment

The receptionist will inform patients who present to the Physiotherapy Outpatient Department at Fairfield Hospital with a referral for physiotherapy for shoulder pain about the study. She will arrange a routine appointment for assessment/ triage and provide an Information Sheet. When the patient subsequently presents for assessment, the receptionist will ask the patient whether they are willing to participate. Volunteers will be provided a Consent Form. This process will obviate the need for the assessing physiotherapist to recruit subjects. Those patients interested in participating will be consented by another physiotherapist, who is not involved in the provision of treatment.

Patients who decline to participate will be assessed and treated according to the usual procedures for the Physiotherapy Department and treatment will not be withheld in any way.

Randomisation

Prior to the study, a researcher not involved in data collection or treatment will generate a randomisation sequence. Labelled pieces of paper with the intervention arm will be placed in sealed opaque envelopes according to the randomisation sequence. The envelopes will labelled with a subject number between 1 and 20. Subjects will be allocated consecutively according to their entry number into the study. The envelopes will kept at University of Western Sydney by a researcher not involved in measurement or treatment of subjects, and will be released to the hospital as each block sequence is completed. The Receptionist shall keep the envelopes in a secure location concealed from therapists and assessors.

Protocol

Prior to enrolling in the study, a physiotherapist will assess volunteers by:

- Completing a history.
- Performing a physical examination.
- Ensuring that inclusion criteria are satisfied.
- Ensuring that exclusion criteria are satisfied.

Volunteers who satisfy the above criteria will be invited to participate in the study and then will be consented by another physiotherapist not involved in the provision of treatment before the patient is returned to the treating physiotherapist.

After written informed consent has been provided, the treating physiotherapist will open the next sealed envelope in the block sequence and assign the subject (by number) to the assigned intervention.

Standardised outcome measures will then be collected.

Intervention A

Subjects will be given individualised exercises according to a recommended protocol from the literature (Holmgren et al 2012). Specifically, the protocol advocates:

- Exercise performed within tolerable levels of pain/ discomfort.
- Some exercises that reduce the subacromial space.

Intervention B

Subjects will be given individualised exercises according to a protocol that:

- Excludes exercise in the presence of pain.
- Excludes exercises that reduce the subacromial space.

Compliance

Subjects from both groups will then be given a diary to record their daily exercise levels and compliance with the assigned exercise protocol. The diaries will also record medication use.

Duration

Subjects from both groups will attend for physiotherapy for a maximum of 8 treatment sessions, over 12 weeks, with an interpreter as required.

Outcome Measurements

Outcomes will be collected by the treating physiotherapist at recruitment. Subsequently, another physiotherapist blinded to intervention, will collect outcomes at:

a. 6 weeks (mid intervention)
b. 12 weeks (conclusion of intervention)
c. 6 month follow up

Primary Outcomes

a. PSFS (limited to 3 items) (Stratford et al 1995)
b. Pain levels using Visual Analogue Scales (VAS) (Williams et al 1995).
c. Compliance measured by daily exercise diary and drop outs.

Secondary Outcomes

a. Shoulder range of abduction and flexion using a hydro-goniometer (Green et al, 1998).
b. 13 point global rating of change (Kamper et al 2009)
c. Shoulder Pain and Disability Index (SPADI) (Roach et al 1991)
d. Pain Self Efficacy Questionnaire (Nicholas 2007)
e. Patient expectations measured using the Patient Shoulder Outcome Expectancies (PSOE) and Patient Shoulder Expectancy Fulfilment (PSEF) (O'Malley et al 2004)

Statistical Power

A pilot phase will be integrated into the trial to inform trial feasibility for a larger trial; specifically to inform power analyses to determine participant numbers for the complete project, which will be an equivalence study. After the first twenty participants have attended their follow-up appointment, data will be evaluated by an independent statistician to inform feasibility and subject numbers for a larger trial.

Expected Duration of Study and Start Time

The pilot trial will be expected to commence once ethical approval has been granted. It is anticipated that the trial phase will be completed within a year, based on current numbers of referrals for this condition within our department. Once the pilot phase has been completed statistical analysis will be performed to determine trial feasibility and to inform final numbers required for a larger trial. It is anticipated that approximately 200 participants would be required based on provisional power analyses to detect a medium effect size of ½ SD for the primary outcome of pain, measured on visual analogue scales and allowing for a drop out rate of 20% of participants, with a significance level of 0.05 and power of 80% (Winer, 1971). With these proposed numbers, it is expected the trial will take 3 years. However, this is subject to more specific analysis following the completion of the pilot phase and timeframes will be revised accordingly.

Analyses

A blinded assessor not involved in the treatment of subjects, and unaware of subject allocation, will perform data analyses. Planned Contrasts within a Repeated measures ANOVA will be employed to describe within- and between-group differences for each continuous outcome measure. Exercise compliance and medication use will be compared using Chi Square analyses, since data will be categorical. Data will be analysed according to the intention-to-treat principle to account for drop-out (Peat, 2001).

References

1. Green S, Buchbinder R, Forbes A and Bellamy N (1998) A Standardized Protocol for Measurement of Range of Movement of the Shoulder Using the Plurirneter-V Inclinometer and Assessment of its Intrarater and Interrater Reliability. Arthritis Care and Research, Vol 11 (1) 43-52.
2. Holmgren T, Bjornsson Hallgren H, Oberg B, Adolfsson L, Johansson K. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. BMJ. 2012;344:e787.
3. Kamper S, Maher C & Mackay G (2009) Global Rating of Change Scales: A Review of Strengths and Weaknesses and Considerations for Design. The Journal of Manual & Manipulative Therapy. 17(3) 163-170.
4. Murrel G & Walton J (2001) Diagnosis of rotator cuff tears. Lancet 357(9258) 769-770.
5. Nicholas, M. K. (2007). The pain self-efficacy questionnaire: Taking pain into account. European Journal of Pain, 11(2), 153-163.
6. O'Malley KJ, Roddey TS, Gartsman G & Cook K (2004) Outcome Expectancies, functional outcomes, and expectancy fulfilment for patients with shoulder problems. Medical Care 42(2) 139-146
7. Roach K, Budiman-Mak E, Songsiridej N & Lertratanakul Y (1991) Development of a shoulder pain and disability index. Arthritis Care and Research 4(4):143-149.
8. Scott J & Huskisson E (1976) Graphic representation of pain. Pain 2:175-184
9. Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.
10. Winer B (1971) Statistical principles in experimental design 2nd Edition. New York : McGraw-Hill.