

Ginn K and Cohen M. Exercise Therapy for Shoulder Pain Aimed at Restoring Neuromuscular Control: A Randomized Comparative Clinical Trial. Journal of Rehabilitative Medicine 2005; 37:115-122.

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Design: Randomized clinical trial

Objective: To compare the effectiveness of exercise therapy aimed at restoring neuromuscular control mechanisms at the shoulder with other conservative interventions for the treatment of chronic shoulder pain with and without accompanying stiffness.

Population /sample size/setting:

- 138 volunteer patients (mean age = 55, 82 males, 56 females) with unilateral shoulder pain of local mechanical origin with or without accompanying stiffness of at least one month duration were recruited from a large metropolitan public hospital in Australia.
- Eligibility criteria included shoulder pain of local mechanical origin which was exacerbated by active shoulder movements, age greater than 18, and the ability to understand spoken English.
- Exclusion criteria included bilateral shoulder pain, shoulder pain associated with instability, pain due to an inflammatory or neoplastic disorder, pain referred from vertebral column structures, or pain due to trauma within the previous 4 weeks.
- All participants completed a standardized interview and musculoskeletal assessment to obtain baseline outcome measurements of pain intensity, functional impairment, active range of motion, isometric muscle force. Measurements were taken again after 5 weeks of treatment and included a self-assessed symptom improvement measure. Assessors were two senior physical therapists uninvolved with the interventions of the trial and unaware of the treatment group to which the subject had been allocated. The same therapist conducted both the baseline and 5-week measurements on a particular subject.

Interventions:

- All participants were randomized to one of three interventions; 1) exercise therapy (n=48) (aimed at restoring dynamic stabilizing mechanisms and muscle coordination at the shoulder), or 2) subacromial corticosteroid injection (n=48), or 3) a combination of electro-physical modalities and range of motion (ROM) exercises defined as multiple physical modalities treatment (MPM)(n=42). Comparison with an earlier no-treatment trial group was also conducted.
- The exercise therapy intervention included stretches and exercises aimed at lengthening shortened shoulder muscles and strengthening weakened muscles and improving coordination between muscles. This intervention was administered as a home-based daily exercise program with supervision by the physical therapist, once per week to correct and upgrade the intensity/complexity of the exercises. Two physical therapists conducted this intervention.
- The corticosteroid injection intervention consisted of a single injection of 40 mg methylprednisone into the sub-acromial space under local anesthesia with lignocaine administered by one rheumatologist.

- The MPM intervention consisted of a combination of electro-physical modalities, passive joint mobilization, and ROM exercises for functional arm movements. The specific treatment for each of the subjects was individually determined by the treating physical therapist (PT). This intervention included passive joint mobilization and electro-physical modalities twice a week and a daily prescribed exercise program. Six PTs participated in this intervention.

Main outcome measures:

- The primary outcome variable used to measure pain intensity was the 10cm vertical visual analog scale (VAS) pain score. Functional impairment was measured using an individually standardized self-reported score for 9 specific upper limb tasks on a 4-point scale of increasing difficulty ranging from zero to 3. Patient-perceived improvement in symptoms was measured using a self-report with a 3-point scale which included “getting better”, “staying the same”, and “getting worse”. Active abduction and flexion ROM were measured using the photographic method described by Ginn (1997).
- Intra and inter-tester reliability of the two independent assessors was calculated. Intraclass correlation coefficients demonstrated good to excellent intra-rater reliability (0.68-0.91) and excellent inter-rater reliability (0.88-0.94) for all outcome measurements.
- Eleven participants were unavailable for reassessment at the end of the 5-week intervention period.
- Baseline characteristics and outcome variables did not differ between the three intervention groups.
- Patient-perceived improvement in symptoms showed no difference between the 3 intervention groups at the end of the 5 week treatment period.
- The mean/median changes in all other outcome measurements showed that all participants improved significantly by the end of the 5 week treatment period with no differences in the intervention groups. The improvements in most of the outcome measures were also similar in both the PR and P subgroups.

Authors’ conclusions:

- For participants with chronic shoulder pain with or without accompanying stiffness, exercises aimed at restoring dynamic stabilizing mechanisms and muscle coordination at the shoulder, or a single corticosteroid injection, or a combination of various physical modalities and ROM shoulder exercises each resulted in a significant reduction in pain and increase in function over a 5 week period. Statistically significant decreases in pain intensity and increases in functional ability, abduction force and ROM were reached by participants in each intervention group at the end of 5 weeks.
- There were no significant differences in the mean/median changes between intervention groups in any of the outcome measurements or in patient perceived improvement after 5 weeks of treatment.
- Results indicate a 65% decrease in pain intensity, a 35% improvement in functional capacity, a 10% to 45% improvement in abduction and ROM, and a 20% improvement in abduction force at the end of 5 weeks. 80% of participants reported that their condition had improved at the end of 5 weeks. Not only are these results statistically significant, but

they demonstrate a significant clinical improvement as well after only 5 weeks of treatment.

- The exercise therapy intervention used in this study for the treatment of shoulder pain deserves greater consideration than the other two interventions for several reasons. This exercise regimen is pain-free, has no adverse side-effects, is basically patient managed as a home-based program, is suited for motivated patients, and is less costly.
- The exercise therapy intervention used in this study is a safe and effective treatment approach for patients with chronic shoulder pain, with or without stiffness.

Comments:

- The participants and the physical therapists or physician treating the participants could not be blinded to the intervention received by each participant. However, the two physical therapists conducting the baseline and 5-week outcome assessments were blinded to the participants' intervention groups.
- Two of the interventions were individually and rationally tailored for each participant by the treating physical therapist in order to maximize a good outcome. It is possible that the positive effects of these two physical therapy treatments were due only or primarily to the personal context in which they were administered and not to the biological/mechanical mechanisms of the intervention.
- Participants were randomized into one of three interventions based solely on shoulder pain which is not a well-defined diagnostic category. Specific unknown shoulder diagnoses may not have been evenly distributed among the 3 interventions during randomization causing an imbalance. Since some shoulder conditions may respond differently to an intervention, an imbalance could be a source of uncertainty of the effects.
- The shoulder disability scale used to assess functional limitation of shoulder pain on everyday living was an individually standardized, self-reported score used only in this study. This functional scale was not previously validated and may not be sensitive enough to detect changes in this outcome measurement. It is uncertain whether or not this functional scale has the ability to detect treatment effects.
- The single corticosteroid injection into the shoulder was not performed using guided, ultrasound injection. This leads to uncertainty whether or not the corticosteroid reached the sub-acromial space where it is effective. Perhaps if guided injection was used to insure that the corticosteroid actually entered the sub-acromial space in the shoulder, this intervention would have worked better showing greater treatment effects. An intervention utilizing unguided injections may underestimate their effect.
- The corticosteroid injection intervention included only a single injection and did not include any instructions on shoulder exercises or recommend rehabilitation after the injection. This is not consistent with regular clinical practice where instructions for ROM exercises would have been given post injection. This intervention would underestimate the effect of injections given with rehabilitation.
- The results of this clinical trial do not support or reinforce the findings of previous clinical trials that have found corticosteroid injections to be more effective than physical therapy for the treatment of shoulder pain and dysfunction in the short term.
- Limiting the study protocol to 5 weeks of treatment impacted the ability of the study to achieve maximal therapeutic benefit for many patients within the exercise and MPM

intervention groups, and impacted the ability of the study to reveal the limited, short-term therapeutic benefit for patients in the corticosteroid injection intervention.

- With active intervention being provided, it was impossible to blind patients as to their treatment allocation. Drawbacks of the study include not assessing blinding success and not addressing adverse effects.
- In Table 1, the descriptions of the various P and PR sub-groups, and ROM groups is vague, and they were never clearly delineated in the text of the article. The ROM groupings contribute little to the overall meaning of the trial.
- The results of this clinical trial do support and reinforce the findings of previous clinical trials which have found corticosteroid injections, exercises, and MPM interventions to be effective for the treatment of shoulder pain and dysfunction in the short term.
- The absence of a no treatment group in this study limits its ability to assess whether the changes are due to the natural history of shoulder pain or the passage of time. However, the absence of a no treatment group does not undermine the study, and I agree that this is ethically justified.

Assessment:

- This study is adequate for some evidence that in patients with chronic shoulder pain with or without accompanying stiffness, individually-tailored exercise therapy aimed at restoring dynamic joint stabilizing mechanisms and muscle coordination, or a single unguided subacromial injection of corticosteroid, or a combination of various physical modalities and ROM exercises is equally effective in the short term.

Reference:

- Ginn K, Herbert R, Khouw W, Lee R. A randomised, controlled clinical trial of a treatment for shoulder pain. *Physical Therapy* 1997; 77:802–811.