Bennell K, Wee E, et al. Efficacy of standardised manual therapy and home exercise programme for chronic rotator cuff disease: randomised placebo controlled trial. BMJ 2010;340:c2756.

Design: Randomized clinical trial

Study question: In patients with chronic rotator cuff disease, does a program of manual therapy and home exercise improve shoulder pain and function more than a placebo?

Population/sample size/setting:

- 120 patients (64 men, 56 women, mean age 60) treated for chronic rotator cuff disease in Australia

- Eligibility criteria were age over 18, shoulder pain for over three months, severity of pain at least 3/10 on a 10 point scale, pain on active abduction or external rotation, and a positive "quick test" for shoulder impingement
- Exclusion criteria were resting severity of shoulder pain greater than 7/10, clinical evidence of a complete rotator cuff tear, previous shoulder surgery, x-ray evidence of osteoarthritis, calcification, or previous fracture; systemic pathology such as inflammatory or neoplastic disease, 50% or more restriction of passive ROM in 2 or more planes, anti-inflammatory drugs in the previous two weeks, or recent interventions such as steroid injection, hydrodilatation, or physical therapy

Main outcome measures:

- Both groups had interventions which consisted of a series of individualized visits with a physical therapist on the same schedule: twice weekly for 2 weeks, then weekly for 4 weeks, then every other week for 4 weeks (10 visits total, 30-45 minutes each)
- Randomization was to an active intervention (n=59) or to a placebo intervention (m=61)
    - The active intervention had five components: soft tissue massage, passive mobilization of the glenohumeral joint, scapular retraining, spinal mobilization, and home exercises
        - The intervention incorporated behavioral strategies, education, goal setting, motivation, and positive reinforcement
        - Exercises were done twice daily for one week, then daily for 10 weeks (to the end of the individualized visits); the group was then instructed to maintain a program of home exercise for a further 12 weeks
    - The placebo intervention involved the same number of treatment sessions, but the placebo group received sham ultrasound therapy with a light application of a non-therapeutic gel to the shoulder for 10 minutes each; the group received

no instruction in exercise techniques and no manual therapy; the participants were not instructed to do any home exercises

- Principal outcomes were blindly assessed at the end of 11 weeks (immediately after treatment); the shoulder pain and disability index (SPADI) total scores improved in both groups, but there were no statistically significant group differences for the SPADI total scores, the scores for pain on movement, or overall patient-reported success ("much better")
    - A secondary outcome, internal rotation strength, was 1.1 kg greater for the active than for the placebo group at the end of 11 weeks
- At the 22 week follow-up, the active group had a significantly greater improvement in the total SPADI score than the placebo group (mean SPADI of 20.9 for the active and 28.3 for the placebo group)
    - However, this was not accompanied by statistically significant differences in pain on movement or the percentage of participants reporting a successful treatment outcome (57% of the active group, 41% of placebo group)
    - Some secondary outcomes, such as quality of life scores and SPADI function score, were also significantly better for the active than for the placebo group
    - Both treatment groups had remained significantly better at the end of the study than at baseline
- Attendance at the treatment sessions was equal between groups; 91% of the active group and 93% of the placebo group attended all 10 scheduled PT sessions
- Success of blinding was also measured; 58% of the active group and 34% of the placebo group correctly identified their treatment group at 11 weeks

Authors' conclusions:

- Immediately after treatment, a realistic placebo treatment and an active treatment program produced generally similar benefits on shoulder pain and function (measured by the primary outcome instrument of the total SPADI), with more than a third of participants reporting a successful outcome
    - However, there were significant differences for some objective and subjective measures of muscle strength at the end of 11 weeks
- At the end of 22 weeks, there were significant differences in the SPADI in favor of the active treatment group, even though the 7.1 point difference fell short of the 8 to 13 points reported in the literature as being the minimally important difference
- The significant improvement in both groups may reflect the natural history of rotator cuff disease, but this is not likely given the duration of disability symptoms
    - However, there may have been a considerable placebo response, since both groups expected to benefit from the intervention they received

    - If the placebo response is substantial, the differences between groups can substantially underestimate the total effects of treatment and lead to false negative conclusions about efficacy
- A lack of blinding of the therapists would be expected to favor the active group, but bias in the favor of that group was not apparent in the results
- Although the study showed no additional benefit of active treatment over placebo immediately after the end of treatment (11 weeks), the additional benefits detected at 22 weeks suggest that the benefits of active treatment may accrue over time

Comments:

- Some descriptions lack clarity and make the interpretation of the study more difficult than it probably needs to be
    - A criterion for inclusion was "a positive quick test for shoulder impingement"
    - The term "quick test" is not defined, but the reader is referred to a study (Hawkins 1980) which describes two tests for shoulder impingement: forcible forward flexion of the humerus and internal rotation of the humerus at 90 degrees of forward flexion; the authors of this article make no reference to a "quick test"
    - Since the commonly used clinical tests for impingement are not especially effective at defining shoulder pathology, it is likely that the patients had more than one kind of shoulder condition; this is not necessarily a flaw of the study if the purpose is to select patients with nonspecific shoulder pain for noninvasive treatment likely to benefit them
    - The description of the placebo intervention is also lacking; the participants in that group "received sham ultrasound therapy and light application of a non-therapeutic gel to the shoulder region for 10 minutes each"
        - If this means 10 minutes of sham ultrasound and then 10 minutes of application of a gel, that means that the sessions lasted 20 minutes for the placebo group; if the two were administered as a single intervention, that would mean that the placebo sessions lasted only 10 minutes each
        - However, the authors state elsewhere that the visits lasted from 30 to 45 minutes each
        - The authors refer the reader to studies they have done in the lower extremity for a description of their placebo intervention, but those studies provide a similarly vague mention of sham ultrasound and a non-therapeutic gel, with no indication of the duration of treatment
- The success of blinding was ascertained in the two groups but it is not stated what question the patients were asked; they certainly knew whether they had been

exercising or not, and the nature of the question they were asked would have been important to determine

- In the active group, both manual treatment and exercise are likely to have made contributions to the clinical improvements in that group, and the independent contribution of manual therapy cannot be estimated
- Although there are some unclear parts of the methods and results sections, there are some well-explained points in the discussion section, especially on the likelihood that a strong placebo response may lead to false interpretations of a small placebo-active intervention difference in outcome, and it is likely that providing no treatment would lead to a lack of improvement during the 22 week time interval of observation of this trial

Assessment: Inadequate for evidence that manual therapy adds significantly to benefits obtained from an exercise program (relevant comparisons were not made)

Interesting observation: Manual therapy combined with exercise may be effective in improving pain and function in patients with pain likely to be arising from undefined rotator cuff pathology