Efficacy of standardised manual therapy and home exercise programme for chronic rotator cuff disease: randomised placebo controlled trial

Bennell K, WeeE, Coburn S, Green S, Harris A, Staples M, Forbes A, Buchbinder R (2010) BMJ 340:c2756 doi:10.1136/bmj.c2756

Overview

This article addressed a study that took 120 participants with chronic(>3/12) rotator cuff disease, recruited through medical practitioners and the community, and compared a placebo and active treatment. It was a randomised participant and single assessor blinded placebo controlled trial. It appears to have been scientifically constructed and meets many points on the PEDro scale, eligibility clearly specified, random allocation which was concealed, blinding of subjects and assessor, yet not treating therapists, and outcomes measured for up to 90% of participants.

Introduction

The authors introduce the paper by explaining that shoulder pain is a common musculoskeletal complaint that can have a significant effect on activities of daily living as well as sleep, overall leading to a reduced quality of life. They go on to explain that a large proportion of shoulder pain is described as rotator cuff disease or impingement, with the primary clinical finding of pain with abduction and signs of impingement. Many different treatments such as exercise and manual therapy are used in this population to modify physical elements that may contribute to pain. There is little high quality evidence to confirm/negate the efficacy of such treatments.

Aims & Objectives

The primary aim of this trial was to determine whether a 10 week programme of standardised manual therapy and home exercise delivered by a physiotherapist improves shoulder pain and function more than placebo treatment does in people with chronic rotator cuff disease.

Methods

Persons with chronic cuff disease were recruited between March 04 and November 07 through medical practitioners and through print and radio. Each participant had plain radiographs and were screened over the phone before an examination to determine whether or not they met the eligibility criteria, which are clearly described.

14 MSK physiotherapists were trained to provide both interventions and these were not blind. There is a clear description of the intervention and how the intervention was administered. All participants were assessed at baseline, 11 and 22 weeks by the same blinded assessor. All participants at baseline were asked to rate their expectation of benefit of treatment. The primary outcomes were the shoulder pain and disability index (SPADI), average pain on movement assessed by a numerical rating scale, and participants' perceived global rating of change overall and the SF36.

The authors give a detailed account of how these outcome measures were used. Other outcome measures used were isometric shoulder internal and external rotation and abduction strength using a manual muscle tester. A description of how this was carried out is given. Adherence to treatment was also measured using a log book.

The authors used an intention to treat analysis and used linear regression to measure the mean differences from baseline to each point and between each group. Perceived global change scores were divided into groups and success of blinding using a 1/0 index.

Results

The results indicate 93 % (112 of original 120 participants) completed the 22 week trial, and the raw data is presented in table 3. A graph is used by authors to show the flow of participants through the trial. Groups were similar at baseline, as were expectation of treatment outcomes. Both groups improved at 11 weeks. No statistically significant difference between groups for primary outcomes at this stage. Active group showed statistically greater improvements in both self reported and objective measures of strength. At 22 weeks, there was statistically significant difference in the improvement reported on the SPADI by the active group, although no statistically significant difference in pain on movement between the groups.

Discussion

Both groups improved over time and this may reflect natural recovery. While this study had no 'no treatment' group, other studies in similar populations have found little change in the 'no treatment' group over time. The authors go on to discuss other possible reasons for the results including the fact that recovery could be due to regression to the mean and placebo. Another study reported of chronic conditions response to treatment showed 10% of change could be due to spontaneous recovery and 30% due to placebo. This figure is similar to the 33% improvement in the placebo group of this study.

The authors go on to discuss some elements of the active treatment which warranted consideration. This included that the standardised treatment may have failed to adequately allow for specific physical impairments. Additionally they mention that there was a number of people who failed to complete the exercise programme in the unsupervised period, however when they were removed from the results the analysis didn't differ, so adherence doesn't seem to have affected outcome. The authors compare their results to other similar trials and the possible reasons for differing results

Limitations and considerations

The authors identify the strengths and limitations of their study with the primary limitation being that the therapists were not blind to the group allocation. This is unavoidable in this type of study.

Conclusion

The active treatment did not confer immediate benefits to pain or function in mature adults with rotator cuff disease. However, greater improvements were apparent at follow-up, particularly in shoulder function and strength, suggesting that benefits with active treatment may take longer to manifest.