Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised trial

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ABSTRACT
Objective To compare the effectiveness of subacromial corticosteroid injection combined with timely exercise and manual therapy (injection plus exercise) or exercise and manual therapy alone (exercise only) in patients with subacromial impingement syndrome.

Design Pragmatic randomised clinical trial.

Setting Primary care based musculoskeletal service.

Patients Adults aged 40 or over with subacromial impingement syndrome with moderate or severe shoulder pain.

Interventions Injection plus exercise or exercise only.

Main outcome measures Primary outcome was the difference in improvement in the total shoulder pain and disability index at 12 weeks.

Results 232 participants were randomised (115 to injection plus exercise, 117 to exercise only). The mean age was 56 (range 40–78), 127 were women, and all had had a median of 16 weeks of shoulder pain (interquartile range 12–28). At week 12 there was no significant difference between the groups in change in total pain and disability index (mean difference between change in groups 3.26 (95% confidence interval −0.81 to 7.34), P=0.116). Improvement was significantly greater in the injection plus exercise group at week 1 (6.56, 4.30 to 8.82) and week 6 (7.37, 4.34 to 10.39) for the total pain and disability index (P<0.001), with no differences at week 24 (−2.26, −6.77 to 2.25, P=0.324).

Conclusions In the treatment of patients with subacromial impingement syndrome, injection plus exercise and exercise only are similarly effective at 12 weeks.

Trial registration ISRCT 25817033; EudraCT No 2005-003628-20.

INTRODUCTION
Shoulder pain is common in primary care, accounting for 11–12 per 1000 general practice consultations.1 Prevalence increases with age, peaking at around age 50.2 Shoulder pain is often persistent, with only 50% reporting recovery after 18 months.3 Subacromial impingement syndrome (defined with Neer criteria) is reported to be the most common diagnosis.1 4 5

Several well designed studies in primary care have evaluated the broader concept of “shoulder pain.”7 8 9 Common non-operative treatments include exercise, manual therapy, and corticosteroid injections.10 11 12 13 14 With respect to subacromial impingement syndrome in particular, recent systematic reviews have found beneficial effects with exercise and manual therapy and with corticosteroid injections.15 16 17 18 No large trials have evaluated the combination of these treatments, possibly because in traditional models of service delivery corticosteroid injections are delivered by a general practitioner and exercise or manual therapy by physiotherapists.19

We hypothesised that the use of exercise and manual therapy in the “window” of reduced pain after a corticosteroid injection could result in better outcomes for people with subacromial impingement syndrome. Electromyographic studies have shown that shoulder pain inhibits the rotator cuff muscles and that effective pain relief from subacromial injection of local anaesthetic can improve findings.20 As these two treatments probably work by different mechanisms, the combined treatment approach could be more effective than the single components. Using physiotherapists to deliver both treatments, we examined the short and long term effectiveness of local corticosteroid injection combined with timely exercise and manual therapy compared with exercise and manual therapy alone for people with subacromial impingement syndrome in primary care.

METHODS
We used a pragmatic approach to reflect how treatment is delivered in normal clinical practice. We recruited participants from March 2006 to August 2008. Shoulder pain was defined as pain in the shoulder region, including the upper arm, elicited or exacerbated by active or passive shoulder movement. To be included patients had to be aged 40 and older, have unilateral shoulder pain, subjectively rate their pain as moderate or severe on a 3 point scale (mild/moderate/severe), and have a non-capsular pattern of restriction. Capsular pattern was defined as painful and...
Referred with shoulder pain (n=1588)  
Willing to be screened (n=1152)  
Not eligible (n=920):  
- Age > 40 (n=166)  
- Mild shoulder pain (n=152)  
- Lost more than 25% lateral rotation (n=156)  
- Contraindications to steroid or lidocaine injection (n=22)  
- Evidence of referred pain (n=79)  
- Inflammatory arthritis (n=21)  
- Bilateral shoulder pain (n=92)  
- Previous fracture or dislocation (n=60)  
- Previous physiotherapy or injection in past 6 months (n=144)  
- Neurological abnormality (n=7)  
- Negative impingement tests (n=20)  
- Unable to give informed consent (n=1)  

Not willing to be screened (n=436) 

Subacromial injection plus exercise (n=115)  
Exercise only (n=117)  

Received injection (n=114)  
Given exercise (n=113)  

Did not receive injection plus exercise because of non-attendance (n=1)  
Did not attend for exercise after injection (n=2)  

Not willing to be screened (n=436) 


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limited passive glenohumeral mobility, with lateral rotation relatively more restricted than abduction and medial rotation. This pragmatic definition has been used in a previous study and is based on guidelines from the Dutch College of General Practitioners. Some loss of lateral rotation was permitted but no more than 25% compared with opposite side. Participants also had to show a Neer impingement sign (passive shoulder elevation with scapular fixed) or have positive results on the Hawkins impingement test (shoulder elevation to 90°, elbow flexed to 90°, then passively internally rotate the humerus). Exclusion criteria were known blood coagulation disorders; evidence of referred pain from the cervical spine or internal organs; history of rheumatoid arthritis, polymyalgia rheumatica, or other inflammatory arthritis; bilateral shoulder pain; neurological diagnosis such as cerebrovascular event with shoulder involvement; contraindication to steroid-lidocaine injection; pregnancy or breast feeding; previous fracture, dislocation, or surgery to shoulder, upper limb, neck, or thorax; steroid injections or physiotherapy for the symptomatic shoulder within the previous six months; or inability to provide informed consent.

One author (DPC) and a research assistant recruited potentially eligible participants after screening referrals from general practitioners to the Leeds Musculoskeletal and Rehabilitation Service, a primary care based musculoskeletal service. Once consent was obtained, baseline outcome measures, including demographic variables and potential prognostic variables, were recorded. Simple block randomisation was performed for seven sites based on a computer generated randomisation list. We then randomised participants to one of the two treatment groups using an independent telephone randomisation service and booked appointments to start treatment according to allocation. While awaiting their first treatment appointment, all participants were taught a home programme of pendular exercises, which involve swinging the shoulder forwards and backwards or in a circular motion while letting the arm hang down.

Interventions

The two study arms were subacromial corticosteroid injection combined with exercise and manual therapy (referred to subsequently as injection plus exercise) or exercise and manual therapy alone (the exercise only group). DPC and SJA delivered training on the study arms to the study physiotherapists in a standardised two hour training session. The study physiotherapists were also given a trial manual to reinforce the study protocol. Participants allocated to the injection plus exercise group were injected with a lateral approach at the mid-point of the acromion with 20 mg triamcinolone acetonide mixed with 4.5 ml 1% lidocaine (lignocaine). Physiotherapists with a diploma in injection therapy performed all injections under “a patient specific direction.” The injection could be repeated after six weeks in patients with ongoing moderate to severe pain.

Both groups were given standard advice to avoid activities that caused or provoked pain; stop all sporting activity and training; avoid using the arm for overhead activities; and avoid repetitive movements or activities that could have contributed to the shoulder symptoms for one week.

Both groups received a programme delivered by a physiotherapist that started one week after the subacromial injection or immediately in the exercise only arm. The study coordinator, study physiotherapists, and a national opinion leader (a shoulder physiotherapy specialist) agreed the content of the physiotherapy intervention at a consensus meeting. The intervention comprised manual mobilisation techniques and exercises, selected from a range of commonly used procedures (see appendix on bmj.com). To individualise treatments, the treating physiotherapists chose mobilisation techniques and exercises for each patient from six mobilisation techniques and 23 exercises. Exercises were progressive as deemed appropriate by the treating physiotherapist. Resistive exercises were avoided for two weeks after the corticosteroid injection in line with professional guidelines. The treating therapist was asked to include a manual therapy technique at least once over the course of the participant’s treatment. Manual therapy is the application of specific
techniques by the therapist to mobilise joints and soft
tissues. It was included as some research has shown that
combined with exercise this is more effective
than exercise alone.\textsuperscript{25,26} The patients attended as
many sessions as deemed necessary by the treating
physiotherapist. We ascertained the number of partici-
pants receiving the trial interventions in the two groups
from the physiotherapy records and the therapy log
sheet completed by the treating physiotherapist.

Outcome measures
The primary outcome measure was the shoulder pain
and disability index (SPADI) at 12 weeks.\textsuperscript{27} Scores
range from 0-100 for each of two subscales represent-
ing pain and disability. A total score is obtained by
taking the mean of these two subscale scores; a score of
100 indicates severe pain and disability. We included
global assessment of change compared with baseline
(a five point scale of “complete recovery” to
“much worse”)\textsuperscript{7} as a secondary outcome measure.
Outcomes were measured by self completed question-
naires at baseline and at one, six, and 12 weeks; a staff
member other than the treating physiotherapist pro-
vided the questionnaires. The one week data were col-
clected a week after the injection (before exercise
started) and hence represent the efficacy of injection
alone. Information was also collected on the concomi-
tant use of analgesics.

After 12 weeks the randomised trial finished and all
patients received usual care. Follow-up by postal ques-
tionnaire at 24 weeks ascertained if improvement in
the groups was maintained. The treating physio-
therapist completed treatment log sheets and returned
them to the study office. Information on additional
treatments, referrals, and patients’ satisfaction was
also collected from the 24 week questionnaire and the
therapy log sheets. Treating therapists were also asked
to complete adverse event forms.

Sample size
Williams et al found that plus or minus 10 represented
a clinically important change in the shoulder pain and
disability index.\textsuperscript{28} We therefore calculated our sample
size on the ability to detect a difference in treatment
groups of 10 points or more in this score. Carette et al
reported standard deviations around the mean change
in scores from baseline to three months of 24.3 for
those receiving a combination of steroid injections
and physiotherapy and 24.5 for those receiving physio-
therapy alone.\textsuperscript{20} Using these data, we estimated that we
needed 95 patients per arm to show a significant differ-
ence at the 5% level with 80% power. With allowance
for a 15% dropout rate, we therefore required 112
patients per arm.

Analysis
Patients’ data were analysed according to the rando-
mised group irrespective of deviations from the proto-
col. Results are presented for patients with data
available. In addition to those who were lost to fol-
low-up, some participants for whom we had data at
24 weeks either did not attend for one or more inter-
vening visits or did not fully complete the shoulder
pain and disability index. We excluded patients with
missing data at a particular time point from the analysis
at that time point.

Rasch transformation of pain and disability index
To provide interval scaling, we transformed the ordi-
 nal data from the shoulder pain and disability index by
Rasch analysis, with adequate model fit ($\chi^2=34.46,$
df=36; $P=0.542$) and strict unidimensionality (indepen-
dent $t$ test $<5\%$).\textsuperscript{29}

Statistical tests
We had three primary outcomes of interest at the pri-
mary 12 week end point: change in total score on the
shoulder pain and disability index and in each of the
two subscales for pain and function. Secondary out-
comes included change in the three measures on the
shoulder pain and disability index at each of the sec-
ondary end points, patients’ global assessment of
change at each end point, and subgroup analyses of
patients in the exercise only group who subsequently
required an injection. We analysed covariance of
changes in shoulder pain and disability index mea-
sures, taking baseline values as covariates. We used
Pearson’s $\chi^2$ tests to compare patients’ global assess-
ment of change between groups and an independent
Student’s $t$ test to compare total shoulder pain and dis-
ability index at week 12 between patients in the exer-
 cise only group who subsequently required an
injection and those who did not. Bonferroni correction
for multiple comparisons set the critical significance
to $P=0.005$ for secondary analysis of covariance and to
$P=0.0125$ for Pearson’s $\chi^2$ tests. Analyses were carried
out in SPSS 16.0.2.

RESULTS
Over 30 months we screened 1588 referrals for
shoulder pain (figure). Of the 232 participants
included, 115 were randomised to subacromial injec-
tion plus exercise and 117 to exercise only. Baseline
characteristics were similar in both groups (table 1),
though patients in the exercise only group had slightly

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**Table 1** Baseline characteristics of participants with subacromial impingement syndrome according to treatment group. Figures are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Exercise only (n=117)</th>
<th>Injection plus exercise (n=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age (years)</td>
<td>54.9 (10)</td>
<td>57.2 (10.3)</td>
</tr>
<tr>
<td>Women</td>
<td>67/117 (57)</td>
<td>60/115 (52)</td>
</tr>
<tr>
<td>Median (IQR) weeks of shoulder pain</td>
<td>17 (12-28)</td>
<td>14 (10-26)</td>
</tr>
<tr>
<td>First episode of shoulder pain</td>
<td>81 (69)</td>
<td>78 (68)</td>
</tr>
<tr>
<td>Started after injury</td>
<td>29 (25)</td>
<td>29 (25)</td>
</tr>
<tr>
<td>Employed</td>
<td>89 (76)</td>
<td>72 (63)</td>
</tr>
<tr>
<td>Diabetic</td>
<td>8 (7)</td>
<td>9 (8)</td>
</tr>
<tr>
<td>Taken painkillers in previous 48 hours</td>
<td>58 (50)</td>
<td>60 (52)</td>
</tr>
<tr>
<td>Mean (SD) shoulder pain and disability index:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>47.26 (9.65)</td>
<td>46.25 (7.84)</td>
</tr>
<tr>
<td>Pain</td>
<td>52.02 (9.91)</td>
<td>50.21 (8.13)</td>
</tr>
<tr>
<td>Function</td>
<td>42.49 (11.05)</td>
<td>42.29 (8.52)</td>
</tr>
</tbody>
</table>

IQR=interquartile range.
In the injection plus exercise group 114 participants received one injection, and four participants received a second injection. One participant randomised to the injection plus exercise group did not receive any injection because of non-attendance. One participant in the exercise only group did not attend for any treatment. Six participants in the exercise only group found their pain intolerable and opted to have a steroid injection before 12 weeks. Two participants in the combination group received an injection but did not attend any physiotherapy appointments. Two hundred treatment logs were returned (98 in injection plus exercise group; 102 in exercise only group). The treatment logs indicated that all patients underwent an exercise programme. Some patients did not receive manual therapy (10/98 in injection plus exercise group; 5/102 in exercise only group). The 28 remaining participants for whom we did not have a treatment log had their appointment records checked and had all attended at least one session of physiotherapy. Participants in both groups attended a median of six physiotherapy sessions.

### Primary outcome

Table 2 shows the change in mean scores on the shoulder pain and disability index over time. At week 12 there was no significant difference between the groups for the pain subscale, disability subscale, or total score. Addition of duration of symptoms and employment status as covariates did not affect the results nor did adjusting for additional steroid injections required by patients in the exercise only group (data not shown).

For comparison with the Rasch transformed data, the adjusted mean change in the original total shoulder score required by patients in the exercise only group was 15.84 (95% CI 13.29 to 18.39) for the pain subscale, 15.27 (95% CI 12.71 to 17.83) for the disability subscale, and 21.02 (95% CI 18.46 to 23.58) for the total score.

<table>
<thead>
<tr>
<th>Week 1</th>
<th>No of patients</th>
<th>Exercise only</th>
<th>Injection plus exercise</th>
<th>Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score:</td>
<td>108</td>
<td>-1.53 (-3.11 to 0.05)</td>
<td>-8.08 (-9.69 to -6.47)</td>
<td>6.56 (4.30 to 8.82)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>101</td>
<td>-1.01 (-2.68 to -0.66)</td>
<td>-9.04 (-10.74 to -7.33)</td>
<td>8.03 (5.64 to 10.41)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Disability</td>
<td>-2.01 (-3.68 to -0.34)</td>
<td>-7.16 (-8.86 to -5.46)</td>
<td>5.15 (2.77 to 7.53)</td>
<td>&lt;0.001</td>
<td></td>
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</tbody>
</table>

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<thead>
<tr>
<th>Week 6</th>
<th>No of patients</th>
<th>Exercise only</th>
<th>Injection plus exercise</th>
<th>Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score:</td>
<td>103</td>
<td>-6.88 (-8.99 to -4.76)</td>
<td>-14.24 (-16.40 to -12.09)</td>
<td>7.37 (4.34 to 10.39)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>100</td>
<td>-7.29 (-9.57 to -5.02)</td>
<td>-15.02 (-17.34 to -12.71)</td>
<td>7.73 (4.48 to 10.98)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Disability</td>
<td>-6.43 (-8.57 to -4.29)</td>
<td>-13.50 (-15.68 to -11.31)</td>
<td>7.07 (4.01 to 10.12)</td>
<td>&lt;0.001</td>
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<table>
<thead>
<tr>
<th>Week 12</th>
<th>No of patients</th>
<th>Exercise only</th>
<th>Injection plus exercise</th>
<th>Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score:</td>
<td>106</td>
<td>-13.09 (-15.92 to -10.26)</td>
<td>-16.35 (-19.28 to -13.43)</td>
<td>3.26 (-0.81 to 7.34)</td>
<td>0.116</td>
</tr>
<tr>
<td>Pain</td>
<td>103</td>
<td>-13.29 (-16.39 to -10.19)</td>
<td>-17.11 (-20.31 to -13.91)</td>
<td>3.82 (-0.65 to 8.29)</td>
<td>0.093</td>
</tr>
<tr>
<td>Disability</td>
<td>-12.83 (-15.59 to -10.06)</td>
<td>-15.74 (-18.59 to -12.90)</td>
<td>2.92 (-1.05 to 6.88)</td>
<td>0.149</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 24</th>
<th>No of patients</th>
<th>Exercise only</th>
<th>Injection plus exercise</th>
<th>Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score:</td>
<td>97</td>
<td>-17.05 (-20.23 to -13.88)</td>
<td>-14.79 (-17.99 to -11.60)</td>
<td>-2.26 (-6.77 to 2.25)</td>
<td>0.324</td>
</tr>
<tr>
<td>Pain</td>
<td>96</td>
<td>-16.67 (-19.94 to -13.40)</td>
<td>-16.53 (-17.86 to -11.19)</td>
<td>-0.14 (-6.83 to 2.54)</td>
<td>0.368</td>
</tr>
<tr>
<td>Disability</td>
<td>-16.87 (-20.00 to -13.74)</td>
<td>-14.90 (-18.03 to -11.70)</td>
<td>-1.98 (-6.40 to 2.45)</td>
<td>0.380</td>
<td></td>
</tr>
</tbody>
</table>
pain and disability index at 12 weeks was \(-23.60\) in the exercise only group and \(-28.54\) in the exercise plus injection group (\(P=0.111\)). Though Rasch transforming the score to interval scaling resulted in smaller mean changes in both groups, the difference between the groups was of similar magnitude (original mean 4.94 (95% confidence interval \(-1.15\) to 11.03) vs Rasch 3.26 (\(-0.81\) to 7.34)).

Secondary outcomes

At week 24 there continued to be no significant difference between the groups for the pain subscale, disability subscale, or total score. Adjustment for the necessity for additional steroid injections in the exercise only group during the 24 weeks of follow-up did not affect the results (data not shown). Improvement was significantly greater in the injection plus exercise group at week 1 and 6.

Table 3 shows participants’ global assessment of overall change compared with baseline. At week 1, 50/104 (48%) reported recovery or improvement in the exercise only group compared with 75/97 (77%) in the injection plus exercise group. At week 6, 78/100 (78%) reported recovery or improvement in the exercise only group compared with 86/94 (92%) in the combined injection plus exercise group. By week 12 and 24 the percentage of participants reporting recovery or improvement was similar in both groups. At 12 weeks, however, there was still a higher complete recovery rate in the injection plus exercise group than in the exercise only group (15/101 vs 8/104).

At 24 weeks the proportion still taking painkillers for their shoulder pain was higher in the exercise only group than in the injection plus exercise group (39/102 (38%) vs 28/100 (28%)). Table 4 shows the additional treatments required in both groups. In the exercise only group 37 patients went on to have an injection after the 12 week visit compared with nine patients in the injection plus exercise group. Those in the exercise only group who had an injection had a higher mean score on the total shoulder pain and disability index at 12 weeks (\(n=37\), mean score 40.6, 35.9 to 45.4) than those who did not (\(n=69\), mean score 30.6, 26.9 to 34.3) (independent Student’s \(t\) test \(-3.28\), \(P=0.001\)). These patients also showed a smaller improvement from baseline (\(-7.2\) (\(-11.9\) to \(-2.5\)) in those who received an injection vs \(-16.6\) (\(-20.0\) to \(-13.4\)) in those who did not; \(F=10.10\), \(P=0.002\)). Most participants reported they were satisfied or very satisfied with their care over 24 weeks (91/97 (94%) in injection plus exercise group; 93/104 (90%) in exercise only group). No adverse events were reported in either group.

**DISCUSSION**

In this large pragmatic randomised trial on the management of subacromial impingement syndrome by physiotherapists we found no significant difference in the score on the shoulder pain and disability index at three months in participants who received a combination of injection and exercise compared with those who received exercise therapy alone. In agreement with two other studies investigating single treatments in the management of shoulder pain, we found outcomes at six month were similar in both groups.7,8 There were, however, differences between groups for our secondary outcomes. Significantly earlier improvements in pain and functional disability at one and six weeks were seen in the group given corticosteroid injection combined with exercise therapy.

**Results in context**

Our findings add to the current evidence base, including a head to head comparison of exercise therapy prescribed by a physiotherapist with local steroid injection delivered by a general practitioner, which found similar outcomes at six weeks and six months.7 Although

| Table 3 | Participants’ global assessment of change from baseline |
|-----------------|-----------------|-----------------|
| **Outcome**     | **Exercise only** | **Injection plus exercise** | **P value** |
| **Week 1**      |                  |                  |              |
| No of patients  | 104              | 97               |              |
| Completely recovered | 0               | 3 (3)            |              |
| Improved but still some problems | 50 (48) | 72 (74) | \(\chi^2=24.0, P=0.001\) |
| No change    | 40 (39)          | 21 (22)          |              |
| Worse        | 13 (13)          | 1 (1)            |              |
| Much worse   | 1 (1)            | 0                |              |

| **Week 6**      |                  |                  |              |
| No of patients  | 100              | 94               |              |
| Completely recovered | 1 (1) | 8 (9) | \(\chi^2=14.6, P=0.006\) |
| Improved but still some problems | 77 (77) | 78 (83) |              |
| No change    | 15 (15)          | 6 (6)            |              |
| Worse        | 7 (7)            | 1 (1)            |              |
| Much worse   | 0                | 1 (1)            |              |

| **Week 12**     |                  |                  |              |
| No of patients  | 104              | 101              |              |
| Completely recovered | 8 (8) | 15 (15) | \(\chi^2=5.4, P=0.248\) |
| Improved but still some problems | 81 (76) | 70 (71) |              |
| No change    | 11 (10)          | 12 (12)          |              |
| Worse        | 5 (5)            | 1 (1)            |              |
| Much worse   | 1 (1)            | 1 (1)            |              |

| **Week 24**     |                  |                  |              |
| No of patients  | 104              | 101              |              |
| Completely recovered | 17 (16) | 16 (16) | \(\chi^2=2.3, P=0.672\) |
| Improved but still some problems | 69 (66) | 71 (70) |              |
| No change    | 10 (10)          | 11 (11)          |              |
| Worse        | 5 (5)            | 2 (2)            |              |
| Much worse   | 3 (3)            | 1 (1)            |              |

*For change compared with baseline.
WHAT IS ALREADY KNOWN ON THIS TOPIC

Shoulder pain is common, persistent, and often caused by subacromial impingement syndrome
Exercise, manual therapy, and corticosteroid injections are common interventions in primary care for this condition

WHAT THIS STUDY ADDS

Steroid injection combined with exercise is of similar effectiveness to exercise only at 12 weeks
A third of patients treated with exercise and manual therapy alone do not improve sufficiently by 12 weeks and will opt for a steroid injection
Earlier improvement in pain and function is seen with corticosteroid injection combined with exercise and manual therapy

there was no significant difference between the groups at 12 weeks, we identified the partial improvers or non-improvers by monitoring the additional injections that participants required once the randomised trial finished after 12 weeks, when usual care resumed. In the exercise only group there was a significantly higher week 12 score on the shoulder pain and disability index for those participants who required a subsequent injection from 12-24 weeks compared with those who were treated only with exercise therapy. Results from the current study would suggest that about a third of adults with impingement and moderate or severe shoulder pain will not respond adequately to exercise therapy alone within three months.

In examining results from recent high quality randomised controlled trials for common musculoskeletal problems, Foster et al commented on the trend for no or very small differences between the effectiveness of different approaches when based on long term outcomes (6-12 months).20

Shorter term outcomes might, of course, be more relevant to people disabled with shoulder pain and to practitioners deciding which treatment to choose in clinical practice. A recent US trial comparing corticosteroid injection with local anaesthetic injection for rotator cuff problems also highlighted the importance of looking at early outcomes.31 It was for this reason that we included a one week outcome measure in the current study. We noted rapid improvement from the steroid injection at one week, and the combined injection and exercise protocol resulted in significantly greater improvement in pain and functional disability at six weeks. If early pain relief is a priority, then adding local steroid injection to a course of physiotherapy would seem to be the best option for patients.

In our trial all therapies were delivered by physiotherapists working in a primary care based musculoskeletal service, and no extra NHS resources were required to implement the study interventions. In routine clinical practice in the UK, combining these treatments in a timely fashion could be problematic for practical reasons related to the skills of practitioners and service issues such as waiting lists for physiotherapy. In this study physiotherapists provided both arms of the study; in other large trials different professions have provided the treatment arms.9 31

The need to avoid selection of a heterogeneous group in research into shoulder pain has been highlighted.32 Although clinical classification is difficult, we aimed to exclude conditions for which the study protocol was not appropriate, such as adhesive capsulitis and inflammatory arthritis, and patients with mild shoulder pain and those aged under 40 years. Severe shoulder pain at initial presentation has been shown to be a prognostic indicator for persistent symptoms.33 34 In keeping with two previous studies that excluded patients with low scores on the shoulder pain and disability index,20 35 we deliberately included only patients who rated their pain as moderate or severe because patients with mild pain would not routinely be offered an injection in clinical practice. Of those patients not eligible for the study, 152 (17%) reported mild shoulder pain. Other studies investigating corticosteroid injections have not used the level of pain or degree of functional disability as specific entry criteria.20 41 We excluded patients aged 40 and under to avoid including younger patients with subacromial impingement related to a sporting injury, who are not usually offered steroid injections as an initial treatment, which was the consensus view of the physiotherapists who designed the intervention package. A recent study indicated that nearly 80% of shoulder pain is found in patients aged 40 and over2; our study therefore reflecting the age group with the highest prevalence of shoulder pain.

Limitations of study

Because of this study’s pragmatic design, participants were not blinded to their interventions and there could have been a placebo or non-specific effect caused by the injection. We therefore accept that the total treatment response probably includes both treatment and associated placebo effects, as is the case in routine clinical practice.42 We did not set out to examine which component of the non-pharmacological intervention (exercise or manual therapy, or both) is effective. Although evidence is emerging about the efficacy of certain interventions—for example, exercise combined with manual therapy seems more effective than exercise alone for subacromial impingement syndrome,23 26 and ultrasound guided injections might have better outcomes than “blind” injections43—questions about the optimal use of injection and physiotherapy interventions remain and continue to be important for future research.

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Data sharing: The dataset will be available from the corresponding author as part of an academic collaboration.


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