EXTENDED REPORT

A pragmatic randomised controlled trial of local corticosteroid injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care

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Objectives: To compare the long term effectiveness of local steroid injections administered by general practitioners with practice based physiotherapy for treating patients presenting in primary care with new episodes of unilateral shoulder pain.

Methods: Adults consulting with shoulder pain were recruited by their general practitioner. Patients were randomly allocated to receive either corticosteroid injections or community based physiotherapy. Primary outcome was self reported disability from shoulder problems at six months. Secondary outcomes included participant's global assessment of change; pain; function; "main complaint"; range of shoulder movement; co-interventions. A study nurse unaware of the treatment allocation performed baseline and follow up assessments. Analysis was by intention to treat.

Results: Over 22 months 207 participants were randomised, 103 to physiotherapy and 104 to injection. Prognostic variables were similar between the two groups at baseline. Mean (SD) improvements in disability scores at six weeks were 2.56 (5.4) for physiotherapy and 3.03 (6.3) for injection (mean difference=–0.5, 95% confidence interval (95% CI): –2.1 to 1.2) and at six months were 5.97 (5.4) for physiotherapy and 4.55 (5.9) for injection (mean difference=1.4, 95% CI –0.2 to 3.0). A "successful outcome" (a minimum 50% drop in the disability score from baseline) at six months was achieved by 59/99 (60%) in the physiotherapy group and 51/97 (53%) in the injection group (percentage difference=7%, 95% CI –6.8% to 20.4%). Co-interventions were more common in the injection group during follow up.

Conclusion: Community physiotherapy and local steroid injections were of similar effectiveness for treating new episodes of unilateral shoulder pain in primary care, but those receiving physiotherapy had fewer co-interventions.

Systematic reviews of randomised controlled trials evaluating treatments for shoulder problems have been inconclusive about their clinical and cost effectiveness.[1–4] Overall, the best evidence relates to the use of local steroid injections. Four explanatory trials, rated by the above reviewers to have "good" methodologies, showed a small advantage of triamcinolone injection over placebo injection, non-steroidal anti-inflammatory drugs (NSAIDs), or physiotherapy for short term reduction in pain when used in hospital settings for participants with rotator cuff problems.[5–8] In addition, two recent pragmatic primary care based trials demonstrated short term benefit of local steroid injection in participants with capsulitis[9] and synovial disorders of the shoulder.[10]

Yet in the UK, the perceived confidence and competence amongst general practitioners (GPs) in diagnosing and treating shoulder problems remains low.[11] Only 22–50% of GPs offer steroid injections for shoulder problems, perhaps reflecting many patients dislike of injections.[12 13] This, together with a lack of long term evidence for the effectiveness of shoulder injections in the broad spectrum of shoulder problems presenting to primary care, raises the question about other treatment choices for shoulder problems. Physiotherapy is one option—it is popular with patients and GPs,[13] and there is a developing body of evidence supporting the effectiveness of exercise therapy, the cornerstone of physiotherapists' management, in the treatment of shoulder pain.[14 15]

We therefore compared the long term effectiveness of local steroid injections administered by GPs with practice based physiotherapy for treating patients presenting in primary care with new episodes of unilateral shoulder pain.

METHODS

Study participants

This study was a multicentre, pragmatic randomised trial based in primary care. We recruited participants aged 18 years and above who consulted their general practitioner with a new episode of unilateral shoulder pain between June 1998 and March 2000. A "new episode" was defined as pain in the shoulder region, including the upper arm, elicited or exacerbated by active or passive shoulder movement, and no consultation for this pain in the affected shoulder in the previous 12 months. Exclusion criteria were a history of inflammatory arthritis, polymyalgia rheumatica, or gross structural or neurological abnormality of the shoulder; contraindications to local steroid injection; history or examination leading to a suspicion of potentially serious disease; referred pain from neck or internal organs; clinical findings of ruptured rotator cuff; previous fracture or surgery to shoulder, upper limb, neck, or thorax; previous physical therapy for shoulder pain within the past 12 months; pregnancy or breast feeding.

Abbreviations: CI, confidence interval; GPs, general practitioners; NSAIDs, non-steroidal anti-inflammatory drugs; VAS, visual analogue scale

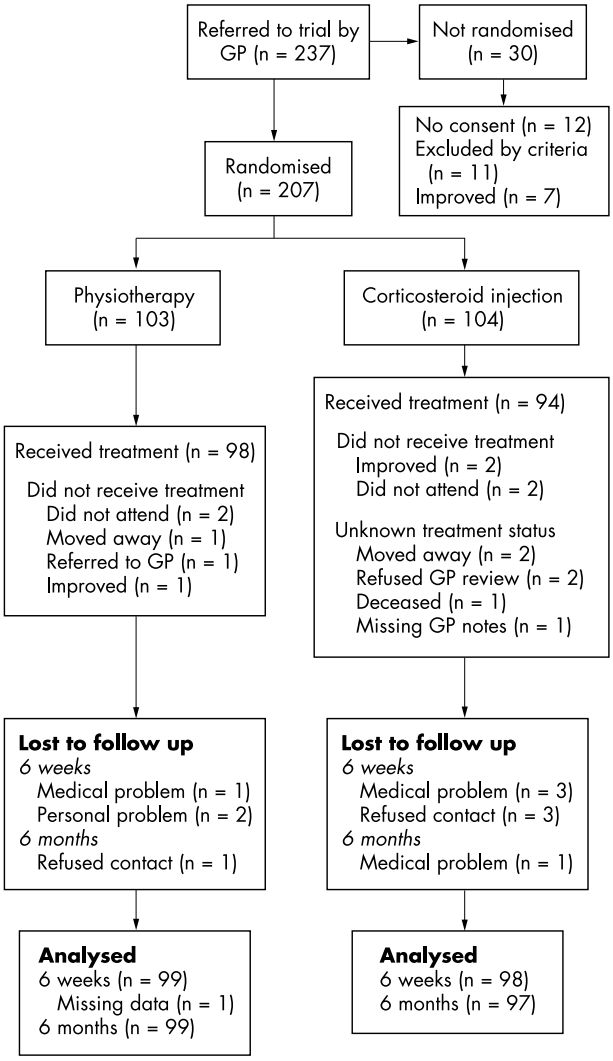

Figure 1 Patient recruitment, randomisation to treatment group, and follow up rates.

The trial was explained to participants by their GP, who gave them an information leaflet and faxed a registration form to the research centre containing the participant's consent to telephone contact by a study nurse (SMP). Baseline assessments were performed by this study nurse (usually in the participants' homes) within two working days of registration. The nurse obtained written informed consent to randomisation and allocated participants a unique study number. The local research ethics committee of North Staffordshire approved all stages of the study.

Study protocol

Treatment allocation was according to the study number. Numbers were issued in a predetermined random sequence, in blocks of 10 by general practice, generated by a random number table. The number corresponded with that on a sealed envelope issued to the participant by the nurse. Participants were instructed not to open the envelope until the nurse had left. The envelopes contained information instructing the participant to either make an appointment with one of the trial physiotherapists or to return to their GP for a local steroid injection.

Participants allocated to corticosteroid injections were given an injection of 40 mg of methylprednisolone mixed with 4 ml 1% lidocaine (lignocaine) into the subacromial space. The injection was administered by their GP according to a standard technique: the tip of the acromium and head of the humerus were identified by palpation and the injection point (just behind the mid-line in the gap between the acromium and head of the humerus) was marked; the skin was cleaned and the needle inserted perpendicular to the skin pointing slightly upwards under the acromium and local steroid with lidocaine injected easily without resistance. Participants were advised to avoid overuse of the shoulder for 48 hours and told that they could make an appointment to return within four weeks if their symptoms persisted. If they did return, they were offered a second injection.

Physiotherapy was delivered by 13 experienced musculoskeletal community physiotherapists. Treatment consisted of up to eight × 20-minute individual physiotherapy sessions delivered within a six week period. The content of the physiotherapy package was developed by consensus to represent best evidence and current practice for pain relief and mobilisation for shoulder problems.[16] The minimum physiotherapy intervention given to all participants was advice and instruction on pain relief plus active shoulder exercises, reinforced by a home programme. Additional treatments, including ultrasound and manual therapy, were given according to the participant's symptoms.

Outcome assessments were performed by the study nurse, who was unaware of the treatment allocation, before randomisation and at six weeks and six months after randomisation. The baseline assessment also included demographic variables, medical history, and potential prognostic variables. General practice case notes were reviewed when follow up was completed by two assessors (SMP and ET). Treatment sheets were completed by the treating physiotherapists and forwarded to the research unit.

The primary outcome measure was disability at six months measured using a shoulder disability questionnaire previously validated for use in primary care.[17] Scores on the questionnaire range from 0 to 23; 23 indicates severe disability. The results were analysed in two ways: (*a*) mean change in disability score from baseline, and (*b*) the proportion who achieved a "successful outcome"; in this study a "successful outcome" was defined as a halving of a patient's disability score from baseline. This was based on data from a previous observational study using the shoulder disability questionnaire,[17] which reported that 50% of primary care consulters with shoulder pain followed up for six months achieved at least a halving in their disability score.[18] Secondary outcomes were participant's global assessment of change compared with baseline, measured on a five point scale of "complete recovery" to "much worse"; pain severity and impairment of function, each measured on a 10 point numerical rating scale; severity of "main complaint", measured on a 10 cm visual analogue scale (VAS)[19]; range of movements (active and passive shoulder abduction and rotation, flexion/extension and rotation of neck); number and type of co-interventions (questionnaire and case note review).

Statistical analysis

As indicated above, a previous observational study[18] suggested that 50% of consulters for shoulder pain achieved a "successful outcome" by six months after consultation.[18] Hence we assumed that 50% of participants would achieve a "successful outcome" in the least effective treatment group. Sample size calculations for this trial were based on the ability to detect a difference of 20% in "successful outcome" between the two treatment groups—that is, 70% achieving a "successful outcome" in the group receiving the more effective treatment. We estimated the target sample size at 105 participants in each group (allowing for a 10% dropout rate, two tailed, $\alpha=0.05$, $1-\beta=0.8$).[20] Intention to treat and "on treatment" analyses were performed by a person unaware of the treatment allocation. All hypothesis tests were two tailed with $\alpha=0.05$. We

Table 1 Baseline characteristics of participants according to treatment group. Values are numbers (percentages) of participants where not otherwise indicated

	Physiotherapy (n=103)	Injection (n=104)
Demography		
Age in years (mean (SD))	57.5 (13)	57.6 (14)
Sex (male)	53 (51)	44 (42)
Social class (manual)	60 (58)	53 (51)
Pain and function (shoulder)		
Shoulder pain today	96 (93)	99 (95)
Severity of pain in day (median (IQR*))	5 (4–7)	5 (4–6)
Impairment of function (median (IQR*))	4 (2–6)	3.5 (2–5)
Main complaint (median (IQR*))	52 (38–77)	54 (43–74)
Duration of pain/stiffness in days (median (IQR*))	51 (21–120)	58 (28–128)
Sudden onset or injury	41 (43)	48 (51)
Ever had neck problems	59 (58)	57 (57)
Work		
Employed	49 (48)	48 (46)
Time off work	10 (12)	6 (8)
General health		
EuroQol (median (IQR*))	0.66 (0.26–0.76)	0.69 (0.52–0.76)
Longstanding medical condition	61 (59)	59 (57)
Taken pain killers in past 48 hours	73 (71)	73 (70)
Movement (in affected shoulder)		
Restriction in active abduction†	78 (76)	76 (73)
Restriction in active external rotation‡	22 (21)	9 (9)
Restriction in passive external rotation‡	14 (14)	7 (7)
Painful arc of abduction (yes)	94 (91)	103 (99)
Neck restrictions (severe)	28 (27)	28 (27)
Disability		
Dressing	93 (93)	90 (92)
Washing	32 (31)	25 (25)
Sleeping	92 (92)	98 (96)
Household	72 (71)	71 (68)
Carrying/reaching	95 (94)	95 (92)
Disability score (mean (SD))	10.9 (4.4)	11.0 (4.7)

*IQR, interquartile range; †subjects not achieving maximum (180°) active abduction; ‡subjects with restriction of greater than 50% compared with non-involved arm.
Data were not available for all cases for some characteristics.

compared groups with χ^2 test for nominal variables, and calculated point estimates with associated 95% confidence intervals (95% CI) for mean differences in disability score, and difference in the proportion of participants with a "successful outcome". Analysis was performed using Stata 6.0.[21]

RESULTS

Study group

Thirty eight GPs from nine practices registered 237 subjects. Of these, 207 (110 women) were randomised: 103 to receive physiotherapy and 104 injection. The numbers of participants recruited by the different practices was variable. Participants' baseline characteristics and the allocation of interventions were similar between the high, medium, and low recruiting practices. Figure 1 shows the progress of participants through the trial, and table 1 shows the baseline characteristics of the study sample. The completion rate of the trial at six months was 95% (196/207) with the following reasons for loss to follow up: five other medical complications, two personal problems, four could not be contacted/refused visit.

Table 2 Number (%) of participants reconsulting, having co-interventions (from GP review) or self reporting visiting practitioners during follow up*

	Physiotherapy	Injection	Difference (95% CI)†
Reconsultation (case note review)			
6 Weeks	18 (18)	26 (27)	−8.7 (−20.1 to 2.9)
6 Months	39 (39)	52 (53)	−14.4 (−27.5 to −0.6)
Co-interventions (case note review)			
6 Weeks	8 (8)	12 (12)	−4.3 (−13.2 to 4.3)
6 Months	32 (32)	40 (41)	−9.1 (−22.0 to 4.2)
Seen other practitioner (self reported)			
6 Weeks	6 (6)	2 (2)	4.0 (−2.1 to 10.7)
6 Months	35 (35)	43 (44)	−9.0 (−22.2 to 4.7)

*Numbers are cumulative totals during follow up; †95% confidence interval for the percentage difference.
The case note review data are presented for the 199 participants (101 physiotherapy/98 injection) who gave permission for access to their medical records.
The self reported data are presented for the 196 participants (99 physiotherapy/97 injection) who completed both the six week and six month follow up.

Interventions

The number of participants actually receiving the trial interventions in the two groups was ascertained by reviews of GP and physiotherapist records. Information on co-interventions was ascertained by review of the GP records and the self reported information collected at follow up. Ninety four participants randomised to injection had a record of receiving it; in four there was no record of an injection in the GP records and GP records were not obtainable for six patients. Of the 103 randomised to physiotherapy, five did not attend for any treatment and 42 participants received the full course of eight sessions. The mean number of sessions received was six. All participants received advice and a home exercise programme. Ultrasound treatment was received by 50 participants on at least one occasion and 76 received mobilisation to their shoulder at least once.

This was a pragmatic study, and after the six week assessment GPs were at liberty to prescribe other treatments if clinically indicated. A higher proportion of those in the injection group than those in the physiotherapy group reconsulted their GP for their shoulder problem or received other interventions (57% *v* 40%, percentage difference= 17%, 95% CI 4% to 31%) (table 2). Twenty nine participants allocated to the physiotherapy group subsequently received a local steroid

Table 3 Primary outcome at six weeks and six months after recruitment according to treatment group: differences in "successful outcome" and mean (SD) improvement in disability score

	Physiotherapy	Injection	Difference (95% CI*)
Number (%) achieving at least 50% drop in disability score			
6 Weeks	30 (30)	35 (36)	−5.4% (−18.2 to 7.6)
6 Months	59 (60)	51 (53)	7.0% (−6.8 to 20.4)
Mean (SD) improvement in disability score from baseline			
6 Weeks	2.56 (5.4)	3.03 (6.3)	−0.5 (−2.1 to 1.2)
6 Months	5.97 (5.4)	4.55 (5.9)	1.4 (−0.2 to 3.0)

*95% Confidence interval.

injection, five received a further course of physiotherapy, and three were prescribed analgesics or NSAIDs. Of those participants randomised to injection, 11 received a second injection (given after the four week treatment period for the injection group), 21 received physiotherapy, and nine were prescribed analgesics or NSAIDs.

Outcome

Intention to treat analysis

Overall, disability from shoulder problems in the physiotherapy group was similar to that in the injection group at both six weeks and six months. Mean (SD) improvements in disability scores were 2.56 (5.4) for physiotherapy and 3.03 (6.3) for injection at six weeks (mean difference=−0.5, 95% CI −2.1 to 1.2) and 5.97 (5.4) for physiotherapy and 4.55 (5.9) for injection at six months (mean difference=1.4, 95% CI −0.2 to 3.0). Thus, although not statistically significant, patients receiving physiotherapy had a better outcome at six months than those receiving injection. A "successful outcome" (a minimum 50% drop in the shoulder disability score from baseline) at six months was achieved by 59 (60%) in the physiotherapy group and 51 (53%) in the injection group (% difference=7%, 95% CI −6.8% to 20.4%) (table 3).

Table 4 shows participants' global assessment of overall change compared with baseline. At six weeks, 77/98 (79%) in the physiotherapy group reported recovery or improvement compared with 69/95 (73%) in the injection group (percentage difference 5.9%, 95% CI −6.2% to 17.9%). A slightly higher number of participants in the injection group than in the physiotherapy group reported complete recovery at six weeks, but this difference had disappeared by six months. At six months, 82/96 (85%) in the physiotherapy group reported recovery or improvement compared with 80/97 (82%) in the injection group (% difference 2.9%, 95% CI −7.6% to 13.4%).

Table 4 Participants' global assessment of overall change from baseline at six weeks and six months after randomisation according to treatment group. Values are numbers (percentages) of participants

Change in shoulder	Physiotherapy	Injection	Total
6 Week follow up	n=100	n=98	n=198
Completely recovered	6 (6)	18 (19)	24 (12)
Some improvement	71 (72)	51 (54)	122 (63)
No change	14 (14)	16 (17)	30 (16)
Worse	6 (6)	8 (8)	14 (7)
Much worse	1 (1)	2 (2)	3 (2)
Missing	2	3	5
6 Month follow up	n=99	n=97	n=196
Completely recovered	23 (24)	17 (18)	40 (21)
Some improvement	59 (61)	63 (65)	122 (63)
No change	7 (7)	6 (6)	13 (7)
Worse	7 (7)	10 (10)	17 (9)
Much worse	0	1 (1)	1 (1)
Missing	3	0	3

Table 5 Secondary outcome measures at six weeks and six months after randomisation according to treatment group

	Physiotherapy	Injection
Shoulder pain in day (median (IQR*))		
Baseline	5 (4–7)	5 (4–6)
6 Weeks	3 (1–4)	3 (1–5)
6 Months	1 (0–3)	2 (0–3)
Shoulder pain at night (median (IQR*))		
Baseline	5 (3–7)	5 (3–7)
6 Weeks	2 (1–4)	3 (0–6)
6 Months	1 (0–3)	1 (0–4)
Function (median (IQR*))		
Baseline	4 (2–6)	3.5 (2–5)
6 Weeks	3 (1–4)	3 (1.5–5)
6 Months	1 (0–3)	2 (0–4)
Main complaint (median (IQR*))		
Baseline	52 (38–77)	54 (43–74)
6 Weeks	26 (10–53)	35 (17–57)
6 Months	11 (2–36)	24 (8–53)
EuroQol (median (IQR*))		
Baseline	0.66 (0.26–0.76)	0.69 (0.52–0.76)
6 Weeks	0.76 (0.66–0.80)	0.76 (0.59–0.80)
6 Months	0.76 (0.69–0.88)	0.76 (0.66–1.00)
Restricted active abduction† (% yes)		
Baseline	78 (76)	76 (73)
6 Weeks	40 (40)	53 (54)
6 Months	31 (31)	38 (39)
Restricted active external rotation‡ (% yes)		
Baseline	22 (21)	9 (9)
6 Weeks	8 (8)	12 (12)
6 Months	7 (7)	8 (8)
Restricted passive external rotation‡ (% yes)		
Baseline	14 (14)	7 (7)
6 Weeks	7 (7)	7 (7)
6 Months	5 (5)	6 (6)

*IQR, interquartile range; †subjects not achieving maximum (180°) active abduction; ‡subjects with restriction of >50% compared with non-involved arm.

Table 5 shows the numerical rating scales for day pain, night pain, and function and the VAS scores for "main complaint" at each follow up assessment. There were no significant differences between the two groups. Similarly, range of movement was comparable between the two groups at each follow up assessment.

Exploratory subgroup analysis failed to show any differences in mean improvement in disability scores between the two interventions related to age, symptom duration, or for participants with or without restricted shoulder movements; painful arc of abduction; restricted neck movements (data not shown).

On treatment analysis

The subgroup of patients who only received the trial interventions (n=111) had lower mean disability scores (10.4 *v* 11.7) at baseline and shorter symptom duration (40 days *v* 60 days) than those who received co-interventions (n=96). It is important to emphasise that comparisons limited to those who received only the trial intervention are not based on a randomised sample, and although there were similar numbers in the physiotherapy (n=57) and injection (n=54) groups, duration of the complaint at baseline was longer in the injection group (58 *v* 42 days). Mean improvement in disability score at six months was higher in the physiotherapy than the injection group (7.51 *v* 5.41, mean difference=2.1, 95% CI 0.03 to 4.2), but this was no longer statistically significant when the results were adjusted for symptom duration, sex, and age (mean difference=1.95, 95% CI −0.11 to 4.01).

DISCUSSION

We present the results from the first large, pragmatic randomised controlled trial to be carried out in the UK, investigating the optimal treatment for new episodes of shoulder pain in patients presenting to GPs. Local steroid injection and primary care physiotherapy were of similar effectiveness. This pragmatic study compared two packages of care for a broad range of shoulder problems. It considered an important practical question: what is the best initial approach for GPs in the early management of shoulder pain—local injection or referral to physiotherapy? The trial was not designed to evaluate a particular corticosteroid or injection technique, or to determine the efficacy of different forms of physiotherapy, or the non-specific effects of multiple contacts between patients and health professionals.

The results from our trial appear to differ from those in two other recent primary care trials from the Netherlands that showed greater short term benefit for local steroid injection over physiotherapy. Winters *et al* compared multiple corticosteroid injections with physiotherapy and manipulation in participants presenting with synovial disorders of the shoulder.[22] Successful outcome (self reported "cure") at five weeks was reported in 35/47 (74%) participants in the injection group compared with 7/35 (20%) in the physiotherapy group, and 13/32 (41%) in the manipulation group. However, outcome was similar in the two groups at two years.[10] van der Windt *et al* reported successful outcome (self reported "much improved" or "complete recovery") at seven weeks in 40/52 (77%) subjects with stiff and painful shoulders (capsulitis) who received up to three intra-articular injections of 40 mg triamcinolone, compared with 26/56 (46%) who received physiotherapy.[9]

There are a number of important differences between our study and these two Dutch studies. Different groups of participants with shoulder problems were included. Winters *et al* defined a group with "synovial disorders of the shoulder" [22] and van der Windt *et al* included subjects with "stiff and painful shoulders".[9] We included patients with a broad range of shoulder problems in our study; they mostly had mild to moderate symptoms typical of the range seen in primary care. Although direct comparisons of the severity and duration of complaints in these three studies are difficult, it appears that participants in our study had lower levels of disability at recruitment. The precise diagnosis and classification of shoulder problems is controversial.[3] Consultant rheumatologists, GPs, and physiotherapists seem unable to agree, casting doubt on the clinical usefulness of currently used diagnostic labels for shoulder problems.[23–26] Independently, two groups have proposed simple classification systems for shoulder pain but their between-rater reliability and validity has not been established in primary care.[27 28] Our approach—the "red flag system"—where classification is restricted to excluding those patients with potentially serious disease (outlined in our exclusion criteria) has been proposed as an appropriate initial stage to managing regional pain in primary care.[29]

Although the three trials compared "injection" with "physiotherapy", the number and site of injection, and the content of the physiotherapy package, differed considerably. For example, passive mobilisation was not permitted in the physiotherapy group in the trial of Winters *et al*,[22] which is not in line with usual physiotherapy practice in the UK or the Netherlands, and ultrasound was excluded from the trial of van der Windt *et al*.[9] Moreover, the trial of Winters *et al* used multiple injections and the majority of participants (75%) randomly allocated to the injection group in the trial of van der Windt *et al* received at least two such injections.[9] Participants in the UK trial received only one injection (though a second injection was available).

The interventions in our trial, after consultation with GPs and physiotherapists, were chosen to reflect current practice in UK primary care. Up to two subacromial injections of methylprednisolone and lidocaine by the GP were allowed, although in practice none of the participants received a second injection within the four week treatment period for the injection group. Most of the GPs had previous experience in injecting shoulders, a standard procedure was agreed, and the GPs attended an initial training session. However, in practice, the accuracy of placement of the steroid injections was not validated. The physiotherapy package was developed to reflect current evidence and best clinical practice following a survey of musculoskeletal physiotherapists in the West Midlands, UK, and consensus meetings of the trial physiotherapists.[16] It focused on self management of shoulder problems, including education and home exercise. Although randomised controlled trials show an apparent lack of efficacy for ultrasound, we included this in our package because of strong belief in its effectiveness by the participating physiotherapists.

In our trial the clinical outcome in the physiotherapy group was comparable with that in the group receiving an injection, but the former group subsequently had a lower GP reconsultation rate for their shoulder problem. There are a number of possible explanations for this. It might reflect the self management aspect of the physiotherapy package, which emphasised ways of helping patients cope with their shoulder problems. Alternatively, it may reflect the increased contact time that had already taken place between physiotherapists and participants as part of the trial intervention. From the GPs' perspective it is a positive outcome, regardless of the explanation, because their work load is reduced with no change in overall patient outcome.

Both the intention to treat and on treatment analyses raise the possibility that outcome at six months was slightly better in the group of patients who received physiotherapy than in those who received injection. This result is in keeping with other recent trials of local steroid injection for soft tissue complaints[9 30 31] and highlights concerns about the long term effectiveness. Our results have policy implications for the management of shoulder problems by GPs. They give patients and clinicians a clear choice when deciding upon optimal treatment for shoulder problems. The choice should take into account factors such as patient and clinician preference, availability of physiotherapy and/or of doctors trained in injection, the need for co-interventions, and concerns about the long term effectiveness of steroid injections. One option is to consider shifting the first line management of shoulder problems in primary care to physiotherapists, and adding local steroid injection when needed for pain control.

In conclusion, subacromial injection with methylprednisolone and primary care physiotherapy were similarly effective at each outcome point, but those receiving physiotherapy had fewer reconsultations with their general practitioners for additional treatment during the follow up period. The high overall success rates in managing shoulder problems in primary care in this and other studies argues against the need for further explanatory trials in this condition. The challenge now is to incorporate these research findings into clinical practice through the development of practical evidence based care pathways.

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