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EXERCISE THERAPY FOR SHOULDER PAIN AIMED AT RESTORING NEUROMUSCULAR CONTROL: A RANDOMIZED COMPARATIVE CLINICAL TRIAL

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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.**

Design: **Randomized control trial.**

Patients: **A total of 138 volunteers with unilateral shoulder pain of local mechanical origin.**

Methods: **Subjects were randomly allocated to receive exercise therapy aimed at restoring dynamic stabilizing mechanisms and muscle co-ordination at the shoulder; or subacromial corticosteroid injection; or a combination of physical modalities and range of motion exercises. Outcome measurements of pain intensity, functional impairment, active range of motion, isometric muscle force and self-assessed improvement were taken at baseline and after 5 weeks of treatment.**

Results: **The mean/median changes in all outcome measurements at 5 weeks indicated that subjects in each treatment group, improved significantly with no difference between the treatment groups. Comparison with an earlier no-treatment trial would suggest that this improvement is greater than that which could be expected by natural recovery.**

Conclusion: **Exercise therapy aimed at restoring neuromuscular control, corticosteroid injection and multiple physical modalities and range of motion exercises are equally effective in the short-term treatment of shoulder pain, with exercise therapy and corticosteroid injection being less costly to administer.**

Key words: shoulder pain, clinical trial, randomized controlled trial, physical therapy (speciality), exercise therapy, intra-articular injections.

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INTRODUCTION

Shoulder pain is a common problem in the general community, accounting for 5% of all general medical practice consultation (1). The shoulder is the fourth most frequent site of musculoskeletal pain reported by patients to general medical practitioners and physical therapists, exceeded only by the neck, back and knee (2, 3). Shoulder pain is associated with significant disability and loss of quality of life as it interferes with many activities of daily living. Significant difficulty with personal care has been reported by 20–30% of elderly study participants (4, 5) with many also reporting difficulty with household duties (4, 5) and one-quarter reporting disturbed sleep (4). Shoulder pain is also associated with significant financial costs to the individual and to the community. In the USA the average cost of a claim for an occupational shoulder disorder is nearly USD16,000 (6) and many workers with chronic shoulder pain which has proved resistant to treatment are unable to resume full-time work (7).

Although exercise therapy is considered to be the most valuable type of treatment for shoulder dysfunction and is the cornerstone of physical therapy treatment (1) only 1 randomized clinical trial has specifically evaluated the effectiveness of exercise therapy for the treatment of shoulder pain (8). In this study which incorporated a no-treatment control group, Ginn et al. (8) demonstrated that an exercise treatment aimed at restoring neuromuscular control, resulted in a greater decrease in shoulder pain and increase in shoulder function in the short term than time alone.

The present clinical trial was performed to compare the short-term effectiveness of the exercise program employed by Ginn et al. (8) with other conservative treatments in subjects with shoulder pain with and without accompanying stiffness. Corticosteroid injection and a combination of various electrophysical modalities and range of motion (ROM) exercises (multiple physical modalities treatment, MPM) were chosen as the comparison treatments because they are the interventions most commonly used in the treatment of shoulder pain (1, 9).

METHODS

This study was approved by the Ethics Committees of The University of Sydney and St Vincent's Hospital Sydney.

Subjects

Volunteer subjects over 18 years of age who were able to understand spoken English were recruited from patients who had been referred to a large metropolitan public hospital with unilateral shoulder pain of more than 1 month's duration, with and without associated stiffness. Subjects were eligible to enrol in the trial if their shoulder pain was of local

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mechanical origin, defined as pain over the shoulder joint and/or into the proximal arm, which was exacerbated by active shoulder movements (8). These criteria were preferred because of the lack of validity and reliability of the current diagnostic classification of shoulder pain (10, 11).

Subjects were excluded if their shoulder pain was bilateral, associated with instability, due to an inflammatory or neoplastic disorder, referred from vertebral column structures or due to trauma within the previous 4 weeks (8). Patients with bilateral shoulder pain were excluded because some outcome measurements relied on comparison with the contralateral side. Patients who had experienced recent trauma to their shoulder were excluded due to the possibility that many aspects of the physical therapy treatments under investigation would be contraindicated. For the purposes of this study shoulder pain was deemed to be referred from vertebral column structures if it was not reproduced by active shoulder movements, if it was reproduced by active neck movements or by palpation of the cervico-thoracic vertebral column, or if paraesthesiae were present in the affected upper limb.

A total of 138 subjects volunteered to participate in this study. Of these, 77 had decreased abduction and/or flexion ROM accompanying their shoulder pain (PR subgroup) and 61 had a painful arc of abduction and/or flexion motion but retained full ROM (P subgroup). Statistical power calculations performed separately for the PR and P subgroups indicated that samples of this size would provide a greater than 80% chance of detecting a 30° change in abduction ROM, assuming standard deviations of 35° (PR subgroup) and 31° (P subgroup), if such an effect existed.

Procedure

All eligible patients presenting to the participating hospital over a 46-month period were fully informed about the study and invited to participate by 1 of the 2 investigators. Subjects were asked to sign a consent form before undergoing a standardized interview and musculoskeletal assessment to obtain baseline outcome measurements of pain intensity, functional limitation, ROM and muscle force. Additional information to help tailor treatment to suit the requirements of each subject in the exercise and MPM treatment groups was also obtained at the initial assessment, e.g. the position of the scapula at rest and the range and force of shoulder internal and external rotation. Two senior physical therapists otherwise not associated with the clinical trial, acted as assessors over the length of the study: the first for the initial 22 months and the second for the remaining 24 months.

Following the musculoskeletal assessment, subjects were assigned to the PR or P subgroup, then randomly allocated to 1 of the 3 treatment groups by 1 of the researchers, using intervention assignment schedules previously prepared separately for those subgroups. Treatment continued for a period of 5 weeks during which time subjects were requested not to commence or change medication. All outcome measurements were then repeated by the original assessor and perceived change in symptoms was recorded. Subjects were specifically requested not to discuss their treatment with the assessor to ensure she/he remained unaware of the treatment group to which the subject had been allocated.

Outcome measurements

Pain intensity was measured on a 10-cm vertical visual analogue scale (VAS) labelled "no pain" and "severe pain" at its extremes. Immediately following performance of a standardized reaching task, incorporating a weight to reproduce shoulder pain if required, subjects were asked to mark the VAS at the point that corresponded to the level of pain they experienced. Functional limitation associated with the shoulder pain was measured using an individually standardized, self-reported score. This questionnaire was developed because no generally accepted shoulder disability scale to assess the change in impact of shoulder pain on everyday living over time, existed at the commencement of this study. Each subject was asked to rate the level of difficulty associated with performing 9 specified upper limb tasks often affected by shoulder dysfunction as well as any tasks identified by that subject that particularly provoked shoulder symptoms. A 4-point scale of increasing difficulty ranging from 0 = "can perform with no shoulder pain" to 3 = "cannot perform because of shoulder pain" was used. Only tasks identified at the initial interview as causing shoulder pain were rated at the follow-up assessment. A functional limitation score was obtained by summation of the scores for each item. Perceived change in symptoms was measured at reassessment by a self-report from the subject using 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 et al. (8). This method was chosen in preference to goniometry as the latter tends to increase symptoms. For subjects in the PR subgroup, the point in range where pain was first felt, termed "onset of pain", and the limit of ROM, termed "ROM", were measured. For subjects in the P subgroup, the painful excursion, termed "painful ROM", was measured. Only the affected side was measured for both subgroups. Hand-behind-back (HBB) range was determined by measuring the distance between T1 spinous process and the radial styloid process with a tape measure with the subject in standing. HBB ROM score was obtained by subtracting the affected side measurement from the unaffected side. A normalized HBB ROM score was chosen because no normative data for this shoulder measurement were available at the commencement of this trial and the clinical judgement of the researchers was that HBB ROM varies considerably in the general population. Isometric abduction force was measured using a hand-held dynamometer, which has been shown to exhibit acceptable reliability when tested on patients with strength deficits (8, 12). The subject lay supine with the shoulder at 90° abduction (or 45° abduction if unable to achieve 90°), the elbow flexed to 90° and the forearm pronated. The dynamometer was placed just proximal to the lateral supracondylar ridge. A "make" test was utilized. The subject was asked to build to a maximum contraction over a 1–2 second period and then hold for a further 5 seconds. Measurements were made bilaterally: on the affected side the force at which pain was first felt was recorded; maximum force produced was recorded for the unaffected side. Isometric abduction force for the affected side was recorded as a percentage of the unaffected side. A normalized abduction force score was chosen because muscle force has been shown to vary considerably in the general population (13). The intra-tester and inter-tester reliability of the 2 independent assessors during active ROM and force measurements was determined prior to the commencement of the clinical trial. Intraclass correlation coefficients ($ICC_{2,1}$) demonstrated good to excellent intra-rater reliability ($ICC_{2,1}$: 0.68–0.91) and excellent inter-rater reliability ($ICC_{2,1}$: 0.88–0.94) for all these measurements (14).

Treatment interventions

The corticosteroid injection treatment was administered by the 1 consultant rheumatologist who was one of the investigators. It consisted of a single injection of 40-mg methylprednisone acetate into the sub-acromial space under local anaesthesia with lignocaine. The patient was encouraged to attempt to use their affected upper limb in a normal manner and to await contact from the investigators at the end of the 5-week treatment period to arrange a time for reassessment.

The target exercise treatment was directed toward the restoration of normal shoulder muscle function in order to restore dynamic stability and muscle co-ordination at the shoulder region. This comprised stretches aimed at lengthening shortened shoulder muscles, exercises aimed at strengthening weakened shoulder muscles, including improving co-ordination between muscles, and motor retraining aimed at restoring scapulohumeral rhythm during the performance of upper limb tasks. All exercises were to be pain-free and subjects in this treatment group were also advised to avoid/limit pain producing activities. Particular emphasis was placed on restoring the normal muscle force couple co-ordination and the dynamic stabilizing function of shoulder muscles. The exercise treatment was devised and upgraded using motor learning principles designed to improve shoulder function by gradually increasing the complexity of the exercises (15). Full range movements of the shoulder, therefore, were considered to be difficult exercises in this treatment group as they involve multiple shoulder muscle force couples. The specific exercises for each of the subjects was individually determined by the treating physical therapist, using data from the initial interview and musculoskeletal assessment and any additional information gathered by the treating physical therapist. The exercise treatment was administered as a home-based, daily exercise program with supervision by the physical therapist once per week, to correct and upgrade the intensity and complexity of the exercises. Two physical therapists, 1 of whom was one of the investigators, administered this treatment over the duration of this

study. Each subject in this treatment group was treated by only 1 of these physical therapists.

The MPM treatment consisted of a combination of electrophysical modalities, passive joint mobilization and ROM exercises. The electrophysical modalities available were interferential therapy, ultrasound therapy, hotpacks and ice packs. Passive joint mobilization at the shoulder, sternoclavicular and acromioclavicular joints could be used. Range of motion exercises involved functional movements of the arm and could incorporate the use of aids to achieve additional range of movement. Abduction, flexion, extension, horizontal flexion and extension and HBB were the shoulder movements considered to be primarily involved in functional arm movements. Consequently, isolated shoulder joint rotation was not an exercise option in this treatment group. The aim of the exercise component of the MPM treatment was to increase the range of hand placement but excessive scapular movement was discouraged. There was no requirement that the ROM exercises be performed in a pain-free manner. Exercises were upgraded from active assisted to active to resisted active exercises using free weights or elastic resistance. The specific treatment for each of the subjects in the MPM treatment group was individually determined by the treating physical therapist using data from the initial interview and musculoskeletal assessment and any additional information gathered. The MPM treatment required twice weekly attendance for application of the passive joint mobilization and electrophysical modality components, as well as daily adherence to a prescribed exercise program. A total of 6 physical therapists administered this treatment option over the duration of the study, each subject being treated by 1 physical therapist only.

Statistics

Perceived change in symptoms was compared using cross tabulations with χ^2 analysis. Where frequencies were too small, categories were collapsed. Following logarithmic transformation as required, mean changes in pain intensity, functional limitation, HBB ROM and abduction force were compared by the use of a 2 (pre post) $\times$ 3 (treatment group) $\times$ 2 (subgroup) analysis of variance (ANOVA) with repeated measures on the first factor. Range of motion outcome measures specific to a subgroup were compared using a 2 (pre post) $\times$ 3 (treatment group) ANOVA with repeated measures on the first factor.

All analyses were performed using SPSS (Statistical Package for the Social Sciences) software except for 95% confidence intervals of medians, which were calculated according to the method described by Altman et al. (2000) (16). Statistical significance was set at $p < 0.05$.

RESULTS

The randomization procedure generated comparable groups at entry to the clinical trial, with the exception of painful and total flexion ROM in the PR subgroup where the exercise group was less affected than the injection group (Table I).

Eleven subjects were unavailable for reassessment at the end of the 5-week treatment period: 6 from the PR subgroup and 5 from the P subgroup. One subject from the injection group died during the treatment period; 1 subject from the exercise group moved interstate; and 9 subjects, 2 from the injection group, 4 from the exercise group and 3 from the MPM group, were unavailable for unknown reasons.

The perceived change in symptoms (Table II) in each treatment group for the total cohort was compared by the use of cross tabulations with χ^2 analysis. This analysis indicated no difference between the treatment groups over the 5 week treatment period ($\chi^2 = 0.91$, df 2, $p = 0.64$). Statistical analysis of the pattern of patient-assessed change in symptoms in each of the treatment groups for the P and PR subgroups was not possible because of the small numbers in some categories which could not be overcome by collapsing categories. Inspection of the raw data in Table II, however, indicates that the response to

Table I. *Descriptive characteristics and outcome measurements at entry to the study*

	Injection group	Exercise group	MPM group	Total cohort
Gender				
Male/female (*n*)	29/19	27/21	26/16	82 /56
Age (years)	55.4 (29–87)	52.6 (22–83)	57.4 (29–90)	55.0 (22–90)
Duration of current symptoms (months) (mean (SD))	7.4 (11.2)	7.3 (8.1)	7.4 (10.9)	7.3 (10.0)
Pain intensity (cm) (median (95% CI))	1.9 (1.0 to 2.9)	1.5 (1.0 to 2.2)	2.6 (1.3 to 3.9)	1.8 (1.4 to 2.5)
Functional limitation (mean (95% CI))	6.9 (5.7 to 8.1)	8.0 (6.8 to 9.2)	8.4 (7.2 to 9.6)	7.8 (7.1 to 8.4)
HBB ROM (cm) (mean (95% CI))	7.9 (5.8 to 10.0)	8.1 (5.2 to 10.9)	8.1 (5.2 to 11.0)	8.0 (6.6 to 9.5)
Abduction force(%) (mean (95% CI))	54 (44 to 64)	58 (46 to 71)	49 (39 to 59)	54 (48 to 60)
Painful abd ROM (deg) P subgroup (mean (95% CI))	53 (40 to 66)	49 (36 to 63)	50 (30 to 70)	51 (43 to 59)
Painful flex ROM (deg) P subgroup (median (95% CI))	19 (1 to 35)	29 (8 to 44)	15 (1 to 60)	22 (14 to 36)
Abd – onset of pain (deg) PR subgroup (mean (95% CI))	55 (43 to 67)	72 (62 to 83)	60 (50 to 71)	63 (57 to 69)
Abd ROM (deg) PR subgroup (mean (95% CI))	79 (63 to 94)	99 (86 to 112)	82 (68 to 95)	86 (78 to 94)
Flex – onset of pain (deg) PR subgroup (mean (95% CI))	72 (60 to 83)	101 (93 to 109)	82 (67 to 97)	85 (78 to 92)
Flex ROM (deg) PR subgroup (mean (95% CI))	92 (81 to 104)	112 (105 to 119)	97 (85 to 109)	101 (94 to 107)

MPM = multiple physical modalities; HBB = hand-behind-back; ROM = range of motion; abd = abduction; deg = degrees; flex = flexion; P = full range of motion despite shoulder pain; PR = decreased range of motion and shoulder pain.

Table II. *Perceived change in symptoms over the 5-week treatment period. Numbers and percentages with 95% confidence intervals indicated in brackets for the total cohort*

	Improved	Stable	Deteriorated
Total cohort	101	19	7
	80% (72–88%)	15% (0–31%)	4% (0–24%)
Injection	35–78%	8–18%	2–4%
Exercise	33–77%	7–16%	3–7%
MPM	33–85%	4–10%	2–5%
P subgroup			
Total	45	7	4
	80% (68–92%)	13% (0–38%)	7% (0–32%)
Injection	18–78%	4–17%	1–4%
Exercise	16–80%	2–10%	2–10%
MPM	11–85%	1–8%	1–8%
PR subgroup			
Total	56	12	3
	79% (68–90%)	17% (0–38%)	4% (0–26%)
Injection	17–77%	4–18%	1–5%
Exercise	17–74%	5–22%	1–4%
MPM	22–85%	3–12%	1–4%

MPM = multiple physical modalities; P = full range of motion despite shoulder pain; PR = decreased range of motion and shoulder pain.

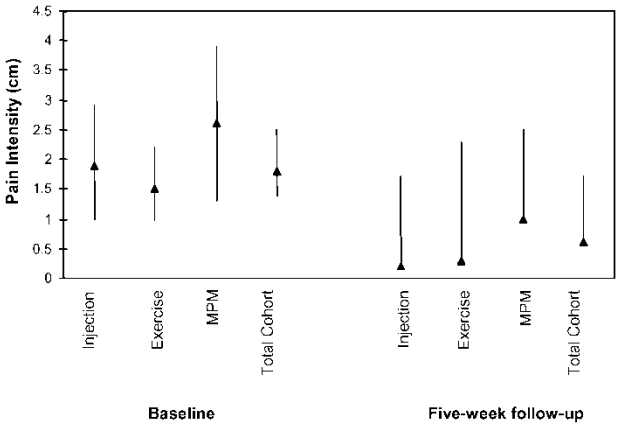

Fig. 1. Pain intensity at baseline and 5-week follow-up. All values are medians (95% confidence intervals); injection = injection group; exercise = exercise group; MPM = multiple physical modalities group.

the treatment interventions in each of the subgroups was similar to those of the total cohort.

The mean/median (95% confidence intervals) of all other outcome measurements at the end of the 5-week treatment period are presented in Table III and Figs 1–5. Except for HBB ROM which did not change significantly but did demonstrate a strong positive trend (Table IV: $F_{(time)1,121} = 3.55$; $p = 0.06$), comparison of the mean changes in the other outcome measurements by ANOVA indicated that subjects in each treatment group improved significantly over the 5-week treatment period with no difference in the manner in which the treatment groups changed over this time (Table IV). The improvement in these outcome measures was similar for subjects with (PR subgroup) and without (P subgroup) accompanying stiffness, except for isometric abduction force where subjects in the P and PR subgroups were responding differently in the different treatment groups (Table IV: $F_{(sub \times treat)2,199} = 3.39$, $p = 0.04$).

DISCUSSION

This randomized clinical trial has demonstrated that, in subjects with shoulder pain with or without accompanying stiffness, exercises aimed at restoring dynamic stabilizing mechanisms and muscle co-ordination at the shoulder, or a single cortico-

Table III. *Outcome measurements at end of a 5-week treatment period*

	Injection group	Exercise group	MPM group	Total cohort
Pain intensity (cm) (median (95% CI))	0.2 (0 to 1.7)	0.3 (0 to 2.3)	1.0 (0 to 2.5)	0.6 (0 to 1.7)
Functional limitation (mean (95% CI))	5.2 (3.9 to 6.5)	4.6 (3.5 to 5.6)	5.3 (4.1 to 6.5)	5.0 (4.4 to 5.7)
HBB ROM (cm) (mean (95% CI))	7.5 (4.9 to 10.2)	6.1 (3.1 to 9.1)	7.3 (4.7 to 10.0)	7.0 (5.4 to 8.6)
Abduction force (%) (mean (95% CI))	66 (55 to 76)	70 (58 to 82)	60 (46 to 75)	65 (58 to 72)
Painful abd ROM (deg) P subgroup (mean (95% CI))	28 (13 to 44)	24 (10 to 37)	30 (8 to 52)	27 (18 to 36)
Painful flex ROM (deg) P subgroup (median (95% CI))	0 (0 to 8)	1 (0 to 10)	1 (0 to 14)	1 (0 to 2)
Abd – onset of pain (deg) PR subgroup (mean (95% CI))	72 (59 to 85)	96 (81 to 111)	74 (60 to 87)	80 (72 to 88)
Abd ROM (deg) PR subgroup (mean (95% CI))	98 (82 to 114)	116 (100 to 132)	97 (81 to 113)	104 (95 to 113)
Flex – onset of pain (deg) PR subgroup (mean (95% CI))	90 (82 to 99)	103 (93 to 113)	89 (74 to 104)	94 (87 to 101)
Flex ROM (deg) PR subgroup (mean (95% CI))	111 (102 to 120)	114 (104 to 124)	104 (92 to 116)	110 (104 to 115)

MPM = multiple physical modalities; HBB = hand-behind-back; ROM = range of motion; abd = abduction; deg = degrees; flex = flexion; P = full range of motion despite shoulder pain; PR = decreased range of motion and shoulder pain.

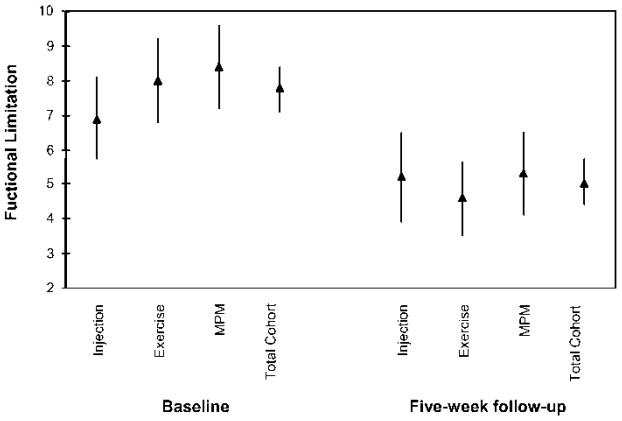

Fig. 2. Functional limitation at baseline and 5-week follow-up. All values are means (95% confidence intervals); injection = injection group; exercise = exercise group; MPM = multiple physical modalities group.

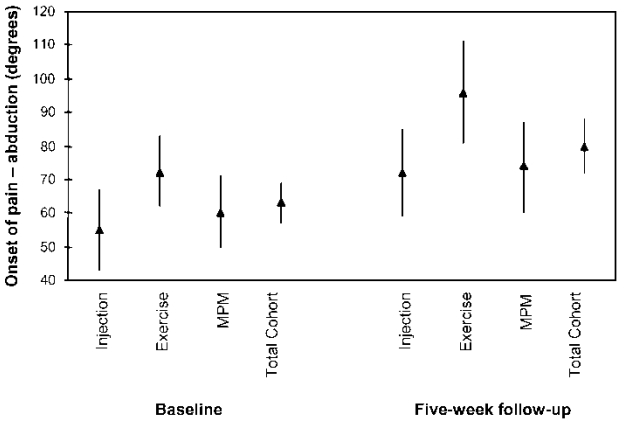

Fig. 4. Range of abduction at onset of pain at baseline and 5-week follow-up. All values are means (95% confidence intervals); injection = injection group; exercise = exercise group; MPM = multiple physical modalities group.

steroid injection, or a combination of various physical modalities and ROM shoulder exercises each result in 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 over this period were achieved by subjects in each treatment group (Table IV). Furthermore, there were no significant differences in the mean/median changes between treatment groups in any of these outcome measurements or with respect to change in symptoms over the 5-week treatment period (Tables II and IV).

In this study pain intensity and functional limitation data were analysed using parametric statistics even though there is evidence that VAS scales do not behave linearly in the upper ranges of these scales (17). However, because the average scores for both pain intensity (1.8 cm, 95% confidence intervals 1.4–2.5 cm) and functional limitation (7.8, 95% confidence intervals 7.1–8.4) in this study were in the low to mid range of the rating scales utilised, we expect that the limitations associated with analysis of ordinal data in this manner would be unlikely to significantly alter the results presented.

The magnitude of the change in the majority of the outcome measurements in this clinical trial would suggest that the improvements in signs and symptoms demonstrated in these subjects with chronic shoulder pain are clinically as well as statistically significant. As all subjects in all treatment intervention groups changed in a similar manner in all outcome measurements, an estimate of the magnitude of change can be made from the total cohort in this clinical trial. Inspection of the changes in the total cohort in Table III indicate approximately 65% decrease in pain intensity (Fig. 1), 35% improvement in functional capacity (Fig. 2), improvements of between 10% and 45% in abduction (Figs 3–5) and HBB ROM, and approximately 20% improvement in abduction force over this period. In addition, 80% of subjects reported that they felt that their condition had improved over the 5-week treatment period (Table III).

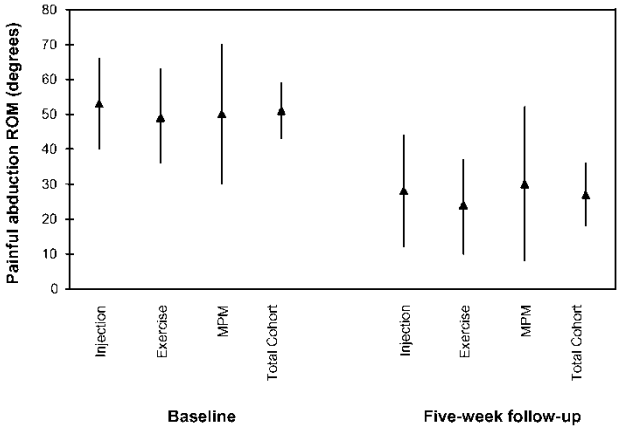

Fig. 3. Painful abduction range at baseline and 5-week follow-up. All values are means (95% confidence intervals); ROM = range of motion; injection = injection group; exercise = exercise group; MPM = multiple physical modalities group.

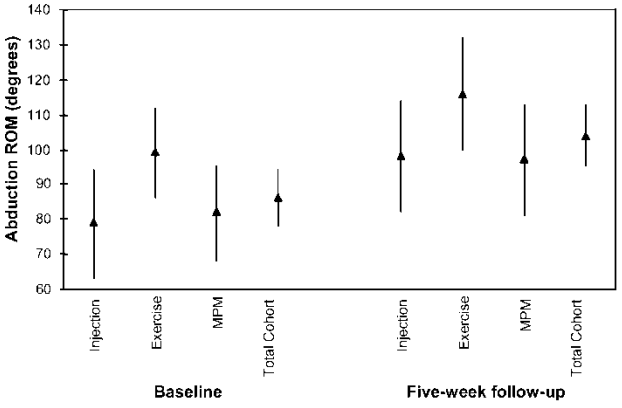

Fig. 5. Total abduction range at baseline and 5-week follow-up. All values are means (95% confidence intervals); injection = injection group; exercise = exercise group; MPM = multiple physical modalities group.

Given that the subjects in this study had been experiencing symptoms for an average of about 7 months (Table I), a decrease of well over 50% in pain intensity, approximately one-third improvement in functional capacity and almost 50% improvement in some ranges of movement after only 1 month of treatment indicates a substantial clinical improvement.

The inclusion of a no-treatment control group in this clinical trial was not appropriate on ethical grounds. At the commencement of the trial the comparison treatments of corticosteroid injection and multiple physical modalities were the standard conservative treatments for shoulder pain and the neuromuscular control exercise treatment had been shown to be superior to time alone in the treatment of shoulder pain (1, 8). As there was no waiting time for treatment at the hospital in which the study was conducted it would have been unethical to withhold standard treatment or treatment of proven efficacy for the 5-week period of the trial.

However, this comparative clinical trial has incorporated the same subject recruitment criteria, methodological design and exercise treatment as Ginn et al. (8), and was conducted on a comparable study population of similar average age and age range, and severity and chronicity of symptoms. Therefore, similar to Ginn et al. (8) in which the exercise treatment resulted in greater decrease in shoulder pain and increase in shoulder function than no-treatment, the improvement demonstrated by the subjects in the exercise treatment group in this current trial would also be greater than would be expected by natural recovery. By association then, the improvement due to corticosteroid injection and MPM treatment would also be greater than that which could be anticipated from natural history alone.

Direct comparison between this study and other clinical trials evaluating the effectiveness of treatment for shoulder pain is difficult because of the lack of uniformity in the design of these studies, including the type of shoulder disorder under investigation, the manner in which treatment interventions were administered, the outcome measurements used and the length of time to follow-up. However, the results of this study do reinforce the findings of those clinical trials, which support the effectiveness of corticosteroid injection (18–22), of exercises (8) and of MPM intervention (22) in the treatment of shoulder dysfunction in the short term. This trial does not support the findings of those trials, which indicate the superior benefit of corticosteroid injection over physical therapy intervention for the treatment of shoulder pain in the short term (21, 22).

Other aspects of the exercise treatment employed in this study, which aimed to improve muscle force couple function and thus indirectly to ease shoulder pain by restoring dynamic, mechanical support mechanisms at the shoulder, warrant consideration. Firstly, if administered in the pain-free manner described in this trial, this treatment approach has no adverse side-effects, unlike corticosteroid injection and the electrophysical modality components of the MPM intervention which have been associated with tissue damage (23, 24). Secondly, being a home-based program, the exercise treatment used in this trial is basically patient managed unlike the corticosteroid injection and the passive mobilization and electrotherapy components of the MPM intervention. In the initial stages regular but infrequent supervision by a physical therapist is needed until the patient learns how to perform the required exercises correctly, how to upgrade exercises and how to assess the need to maintain appropriate exercises. Thus exercise-based treatment should enable motivated patients to take full responsibility for the

Table IV. *Analysis of mean changes between intervention groups over a 5-week treatment period*

Outcome measurement	$F_{(time)}$	$F_{(time \times treat)}$	$F_{(sub \times tr)}$	$F_{(sub \times time \times tr)}$
Pain intensity	$F_{1,120} = 28.10$ $p < 0.00$	$F_{2,120} = 0.17$ $p = 0.84$	$F_{2,120} = 0.08$ $p = 0.93$	$F_{2,120} = 1.48$ $p = 0.23$
Functional limitation	$F_{1,120} = 61.70$ $p < 0.00$	$F_{2,123} = 2.10$ $p = 0.13$	$F_{2,120} = 1.85$ $p = 0.16$	$F_{2,120} = 1.46$ $p = 0.24$
HBB ROM	$F_{1,121} = 3.55$ $p = 0.06$	$F_{2,121} = 1.57$ $p = 0.21$	$F_{2,121} = 0.77$ $p = 0.47$	$F_{2,121} = 0.31$ $p = 0.74$
Abduction force	$F_{1,119} = 7.80$ $p = 0.01$	$F_{2,119} = 0.03$ $p = 0.97$	$F_{2,119} = 3.39$ $p = 0.04$	$F_{2,119} = 0.72$ $p = 0.49$
Painful abduction (P subgroup)	$F_{1,53} = 18.84$ $p < 0.00$	$F_{2,53} = 0.14$ $p = 0.87$		
Painful flexion (P subgroup)	$F_{1,53} = 25.68$ $p < 0.00$	$F_{2,53} = 0.08$ $p = 0.93$		
Onset pain – abduction (PR subgroup)	$F_{1,59} = 29.30$ $p < 0.00$	$F_{2,59} = 0.74$ $p = 0.48$		
ROM – abduction (PR subgroup)	$F_{1,68} = 15.77$ $p < 0.00$	$F_{2,68} = 0.04$ $p = 0.96$		
Onset pain – flexion (PR subgroup)	$F_{1,55} = 10.35$ $p < 0.00$	$F_{2,55} = 1.59$ $p = 0.21$		
ROM – flexion (PR subgroup)	$F_{1,68} = 12.84$ $p < 0.00$	$F_{2,68} = 2.15$ $p = 0.12$		

$F_{(time)}$ = effect of time; $F_{(time \times treat)}$ = effect of time/treatment interaction; $F_{(sub \times tr)}$ = effect of subgroup/treatment group interaction; $F_{(sub \times time \times tr)}$ = effect of subgroup/time/treatment group interaction; HBB = hand-behind-back; ROM = range of motion; P = full range of motion despite shoulder pain; PR = decreased range of motion and shoulder pain.

management of their shoulder problem once formal treatment has ceased. Finally, the home-based exercise treatment with an expected attendance at 4 physical therapy treatment sessions, together with the corticosteroid injection treatment requiring a single visit to a specialist medical practitioner, were less costly to deliver than the MPM treatment which required twice weekly attendance for physical therapy treatment.

Because of the nature of the exercise and MPM treatment interventions used in this clinical trial, it was not possible to keep the subjects or the therapists blind to the treatment received by each subject. The use of a placebo intervention to quantify the non-specific effects of exercise had been ruled out because it is not known which, if any, shoulder exercises afford no therapeutic benefit. In addition a previous attempt to incorporate a comparable and convincing sham treatment had proved impossible (8). Thus constrained, the current clinical trial attempted to minimize the potential threat to internal validity by standardizing the placebo effect across the 3 treatment interventions under investigation. Based on the approach that enhancing contextual effect should improve the outcome of treatment (25, 26), each treatment intervention was delivered in a manner to maximize the subjects' expectation of a good outcome. However, the possibility that the effects of treatment in this trial were due only or primarily to the context in which the treatments were administered and not to the proposed biological mechanisms cannot be ruled out (27).

The manner in which this trial was conducted means that the results are relevant to most clinical situations. Unreliable diagnostic categories were not used to select subjects for this trial. Local shoulder pain was defined by criteria that could be easily elicited from an interview and simple physical examination in any clinical setting. Exercise and MPM treatments were not rigidly predetermined by the researchers in this trial. Reflecting common clinical practice, these interventions were individually and rationally tailored for each subject by the treating physical therapist. Finally, many clinicians were involved in providing the physical therapy treatments that achieved the improvements reported emphasizing the wide applicability of these results.

In conclusion, the results of this study indicate that, in patients suffering from chronic shoulder pain with or without accompanying stiffness:

1. individually-tailored exercise therapy aimed at restoring dynamic joint stabilizing mechanisms and muscle co-ordination or a single subacromial injection of corticosteroid or a combination of various physical modalities and ROM exercises is equally effective in the short term;
2. this short-term improvement is greater than that which could be expected from natural recovery;
3. home-based exercise therapy aimed at restoring neuromuscular control at the shoulder and corticosteroid injection are less costly to deliver than a MPM treatment approach. In addition, exercise therapy does not have the potential risks associated with the corticosteroid injection.

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