Effectiveness of a Group Physiotherapy Intervention in Nontraumatic, Inoperable Painful Shoulder

A Randomized Clinical Trial

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Purpose: The aim of the study was to assess the effectiveness of a group intervention in painful shoulder.

Design: This was a two-arm controlled clinical trial with a 5-wk follow-up and 1:1 allocation ratio with pretreatment and posttreatment assessments in a Spanish hospital in 2015–2016. This study comprised 74 patients with nontraumatic, inoperable painful shoulder. Patients were randomized into two groups: (1) in intervention, patients underwent group rehabilitation exercises supervised by a physical therapist and (2) in control, patients performed the same exercises as the intervention group but in their own home. The main variables were the differences preintervention and postintervention between scores on the visual analog scale, Constant-Murley scale, and Disabilities of the Arm, Shoulder and Hand scale. The mean differences in the main variables were compared between the two interventions (*t* test). Registration code is NCT02541279 (clinicaltrials.gov).

Results: Differences were found in favor of the intervention group: (1) visual analog scale = −0.1 ($P = 0.723$), (2) Constant-Murley = 4.1 ($P = 0.085$), and (3) Disabilities of the Arm, Shoulder and Hand = 14.7 ($P < 0.001$).

Conclusions: Relevant improvements were obtained with our intervention in the Disabilities of the Arm, Shoulder and Hand scale.

Key Words: Shoulder Impingement Syndrome, Shoulder Pain, Physical Therapy Modalities, Clinical Trial, Physiotherapy

(*Am J Phys Med Rehabil* 2018;97:110–115)

Ascertaining effective treatment approaches to nontraumatic shoulder pain is becoming increasingly important due, in part, to the increasing prevalence of this condition (3%–7%),[1] especially among people who perform repetitive manual activities, such as domestic tasks or operating heavy machinery. This has resulted in shoulder pain becoming one of the most frequent reasons for visiting rehabilitation services.[1]

After back and neck pain, shoulder pain is the third leading cause of musculoskeletal pain.[2] Only 50% of new episodes of shoulder pain improve within the first 6 mos, with just 60% improving after 1 yr. The prevalence of painful shoulder ranges from 6.9% to 34% in the general population and represents 1.2% of all consultations.[3]

In 2016, a systematic review concluded that physiotherapy was the first-line treatment for patients with nontraumatic shoulder pain,[4] because it demonstrates short- and long-term effectiveness. Several clinical trials have been conducted to determine the effectiveness of possible interventions to reduce shoulder pain (Table 1),[5–12] such as ultrasound, heat, and supervised therapeutic exercises. These studies mainly assessed improvement in range of motion and pain after the intervention (Table 1).[5–12] However, the interventions examined in these studies were administered individually to each patient (Table 1).[5–12] Because it is of interest to analyze the effectiveness of early group interventions in other disorders,[13,14] and bearing in mind the benefits afforded by group therapy (social and reciprocal support, and cost-effectiveness),[15,16] and the absence of such interventions in nontraumatic painful shoulder (Table 1),[5–12] we carried out a controlled clinical trial to determine the effectiveness of performing manual therapeutic exercises in a group setting as opposed to performing them individually in the home.

MATERIALS AND METHODS

Study Population

The study involved patients treated at San Juan de Alicante University Hospital for nontraumatic shoulder pain who had been referred by the rehabilitation specialist for physiotherapy. According to the protocol, patients are referred for physiotherapy when they are younger than 80 yrs, have no cognitive impairment, and present at least one of the following conditions: nontraumatic rotator cuff tear, tendinitis of the supraspinatus and infraspinatus, subacromial impingement syndrome (any degree), partial or complete tendon tear, or capsulitis. In addition, patients should not present extreme pain (visual analog scale [VAS] ≥ 8) because these patients are referred for other types of treatment. San Juan de Alicante University Hospital covers

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Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.ajpmr.com).

ISSN: 0894-9115

DOI: 10.1097/PHM.0000000000000817

TABLE 1. Intervention studies in patients with stable shoulder impingement syndrome who have not undergone surgery using the VAS at rest, the Constant-Murley, or the DASH scores

Reference Number	Time, Weeks	*n*	Treatment	Results: Difference (Absolute Value) in the Tests Analyzed
Calis et al., 2011[5]	3	52	G1. Ultrasound + hot pack + TE G2. Laser + hot pack + TE G3. Hot pack + TE	VAS: 0.09 (G1 vs. G2), 0.64 (G1 vs. G3), and 0.73 (G2 vs. G3) CMS: 2.45 (G1 vs. G2), 3.03 (G1 vs. G3), and 0.58 (G2 vs. G3)
Kaya et al., 2014[6]	6	54	G1. Kinesio taping + cryotherapy + TE G2. MT + cryotherapy + TE	VAS: 0.54 DASH: 3.06
Engebretsen et al., 2009[7]	6	104	G1. Shock waves G2. TE	VAS: 0.2
Kromer et al., 2013[8]	5	90	G1. IAE + TE+ home exercise program G2. TE+ home exercise program	VAS: 0.6
Santamato et al., 2009[9]	2	70	G1. high-intensity laser therapy G2. US	VAS: 1.69 CMS: 3.66
Şimşek et al., 2013[10]	12 days	38	G1. KT + TE G2. Sham KT + TE	VAS: 0.75 DASH: 15.42 CMS: 12.05
Vas et al., 2008[11]	4	425	G1. Acupuncture + TE G2. Mock TENS + TE	VAS: 1.3 CMS: 0.6
Yildirim et al., 2013[12]	3	100	G1. 15 sessions of US (4 mins) + superficial heat + TENS + TE G2. 15 sessions of US (8 minutes) + superficial heat + TENS + TE	CMS: 9.38

CMS, Constant-Murley Shoulder Score; IAE, individually adapted exercises; KT, Kinesio taping; MT, manual therapy; TE, supervised therapeutic exercises; US, ultrasound therapy.

a health area of approximately 230,000 inhabitants and its services are free and universal.

Study Design and Participants

This was a randomized, single-blind, parallel clinical trial with two arms (intervention and control) with a 5-wk follow-up and a 1:1 allocation ratio. All patients interested in participating in the study who were referred by the rehabilitation specialist to the physiotherapy area of San Juan de Alicante University Hospital between November 2014 and May 2015 were recruited. Patients were randomly assigned to one of the groups following a random number procedure (probability of assignment to each group = 50%). After completion of the intervention, the patients were requested by phone to attend the physiotherapy area to measure the improvement in range of motion and pain. The researchers who evaluated the improvement after the intervention were blinded to the patient group assignments.

Interventions

Once the patients were randomized, subgroups were formed consisting of six patients from the intervention group (intervention patients) and six from the control group (control patients). Because the total number of participants in the study was not a multiple of 12, some subgroups were extended to 13 patients. Each subgroup of 12 patients (or 13) had an initial meeting (start of follow-up) with the physical therapist, involving an informative talk about recommendations, postural hygiene, and the description of a series of exercises to treat their condition. Information sessions for the subgroups were offered on a Monday, Wednesday, or Friday. The exercises were obtained through a literature search on shoulder conditions and were provided to the participants in a printed guide (Supplemental Digital Content 1, http://links.lww.com/PHM/A474).[5,17–25] This guide enabled the patients to perform the exercises at home, as described hereinafter.

Intervention Group

After the information session, the intervention patients in each subgroup were independently telephoned to request their attendance at five consecutive sessions on the days shoulder treatment is offered at our hospital (Monday, Wednesday, and Friday). For example, if the information session was on a Friday, the intervention patients had to attend the following week on Monday, Wednesday, and Friday and the week after that on Monday and Wednesday. To ensure the correct performance of the exercises, at each session, a physical therapist supervised the intervention patients in their performance of the therapeutic exercises indicated in the guide (Supplemental Digital Content 1, http://links.lww.com/PHM/A474). The approximate duration of each physiotherapy session was 1 hr. Two weeks after the last physiotherapy session (end of follow-up), these patients were given an appointment to return for a single session similar to the previous ones. Every day from the beginning (information session) to the completion of follow-up, the patients also

performed the exercises in their own home, with the help of the guide (Supplemental Digital Content 1, http://links.lww.com/PHM/A474).

Control Group

The control patients carried out the exercises indicated by the guide (Supplemental Digital Content 1, http://links.lww.com/PHM/A474) from the beginning of follow-up (information session) until the day before its completion, which coincided with the next day of shoulder treatment for the intervention patients in their own subgroup. On the day follow-up was completed, the control patients were requested to attend the hospital for a group physiotherapy session, similar to those attended by the intervention patients during follow-up.

All the patients, at both the beginning and the end of follow-up, were asked to complete the following questionnaires: VAS,[26] Constant-Murley scale,[27] and QuickDASH scale.[28] In this way, we were able to determine the effectiveness of the intervention in reducing pain, increasing strength, and increasing range of motion.

Variables and Measurements

The main outcome variables were the differences between preintervention and postintervention scores obtained in the tests used (VAS, Constant-Murley, and QuickDASH).[26–28] On the VAS, the patient indicated the intensity of shoulder pain ranging from 0 to 10.[26] The Constant-Murley scale assesses pain,[27] activities of daily living, range of mobility, and strength. Each parameter has an individual score, the maximum total sum of which is 100 points. Higher scores indicate better function. Within this test, a manual muscle tester was employed (Lafayette Manual Muscle Test System) to measure strength. This device was always used by the same physical therapist. Testing was performed with the patient in a seated position, with the arm to be tested flexed to 90 degrees, elbow fully extended, and forearm pronated. The device was applied to the distal part of the forearm and the participant was asked to exert maximum force against resistance. In a standing position, the physical therapist applied resistance with the device using his own strength. Three readings were taken, and the mean strength was calculated in kilograms and then later converted to Newtons. The QuickDASH consists of a 30-question test and evaluates functional limitations in musculoskeletal disorders of the upper limbs.[28]

Secondary variables included sex, affected side (right, left, or both) right-handedness, diagnoses made by the rehabilitation specialist (tendon rupture, supraspinatus tendonitis, subscapularis tendonitis, capsulitis, and subacromial impingement syndrome) and by the physical therapist (limited arm or shoulder movement), and age (years) were measured during the information session to verify the homogeneity of both main groups (intervention and control) in the allocation, follow-up, and losses to follow-up. All the variables were measured by the physical therapist on the last day of the information session, except for the medical diagnoses, which were obtained through the medical history.

Sample Size

The sample size was calculated to determine whether there were differences between the means of the two groups. For this, the following parameters were assumed: type 1 error of 5%, power of 80%, expected difference of 10 points, expected SD of 10 points, 1:1 allocation ratio, and 35% loss to follow-up rate. With these data, the resulting sample size was 34 patients in each group. This calculation was performed using the DASH in a pilot study.

Statistical Methods

Qualitative variables were described with absolute and relative frequencies, whereas quantitative variables were described by calculating means and SD. To determine differences in the homogeneity of the groups in the allocation and in the final analysis, as well as in the losses to follow-up, Pearson's χ^2 test (qualitative variables) and Student's t test (quantitative variables) were used. The loss rate in both groups was compared using the z test. The analysis of the differences between the tests analyzed was performed with Student's t test. All analyses were conducted with a type 1 error of 5%, and for each relevant parameter, its associated confidence interval was calculated. The statistical software used was IBM SPSS Statistics 19.

Ethical Issues

All patients provided written informed consent. The study was approved by the ethics committee of San Juan de Alicante University Hospital on October 28, 2014, (code 14/324) and complies with the ethical principles of the Declaration of Helsinki. The clinical trial was registered on clinicaltrials.gov with reference number NCT02541279. This study conforms to all CONSORT guidelines and reports the required information accordingly (see Checklist, Supplemental Digital Content 2, http://links.lww.com/PHM/A475).

RESULTS

Figure 1 illustrates that of a total of 77 patients invited to participate in our study, 3 were excluded because they did not meet the inclusion criteria, 2 because they were older than 80 yrs, and 1 because of cognitive impairment. This left a total of 74 subjects to be randomized into the two groups: 36 in the intervention group and 38 in the control group.

In Table 2, we see that both groups comprising our sample had a minority of men (~30%), with an average age close to 60 yrs, most were right-handed (almost all patients) with this side being the most affected (~75%), and there was high variability in the prevalence of the different shoulder conditions. Table 2 also shows the analysis of group differences and losses during the study. In the initial allocation, we found no significant differences between the groups, with P values ranging from 0.063 to 1 ($P > 0.05$). However, there were differences between groups in dropout rates (intervention = 0%; control = 34.2%; $Z = 3.56$; $P < 0.001$). For the remaining study variables, no differences were found between the patients who remained in the study and those who dropped out ($0.05 < 0.193 < P < 1$). Finally, there were no differences between the two groups in the patients who finished the study, with P values of greater than 0.104 (>0.05).

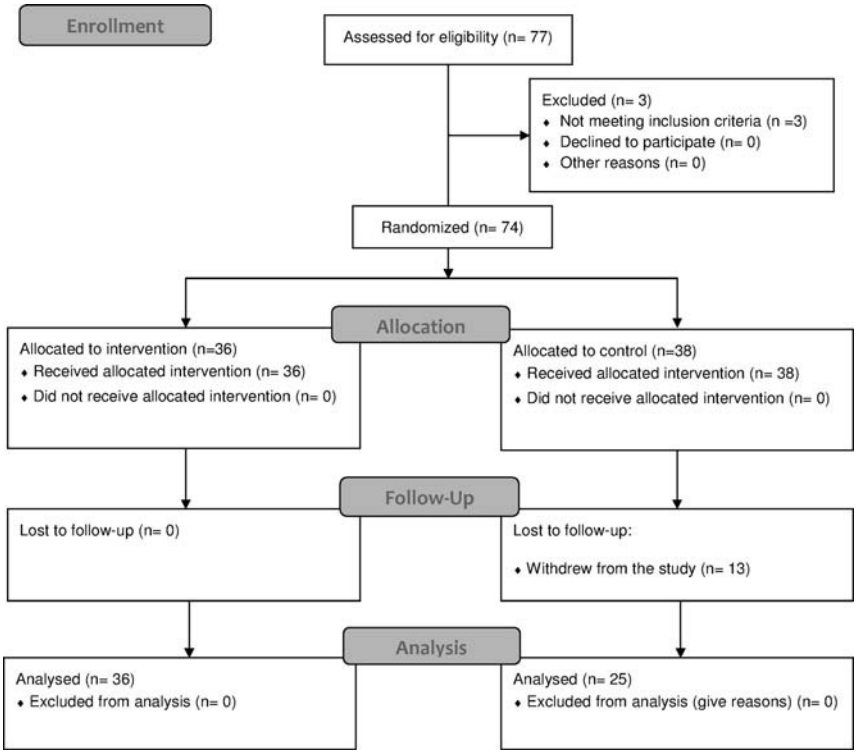

FIGURE 1. The CONSORT flow chart.

TABLE 2. Descriptive analysis for patients who participated in the study

	Allocation[a]			Follow-up[ab]			Analysis[a]		
Variable	Intervention Group (n = 36)	Control Group (n = 38)	P	Withdrew From the Study (n = 13)	Completed the Study (n = 61)	P	Intervention Group (n = 36)	Control Group (n = 25)	P
Male sex	11 (30.6)	12 (31.6)	0.924	3 (23.1)	20 (32.8)	0.743	11 (30.6)	9 (36.0)	0.656
Affected side:									
Right	28 (77.8)	28 (73.7)	0.626	9 (69.2)	47 (77.0)	0.340	28 (77.8)	19 (76.0)	0.477
Left	8 (22.2)	8 (21.1)		3 (23.1)	13 (21.3)		8 (22.2)	5 (20.0)	
Both	0 (0)	2 (5.3)		1 (7.7)	1 (1.6)		0 (0)	1 (4.0)	
Tendon rupture	10 (27.8)	9 (23.7)	0.687	5 (38.5)	14 (23.0)	0.245	10 (27.8)	4 (16.0)	0.282
Right-handedness	36 (100)	37 (97.4)	>0.999	13 (100)	60 (98.4)	>0.999	36 (100)	24 (96.0)	0.410
Supraspinatus tendonitis	14 (38.9)	23 (60.5)	0.063	8 (61.5)	29 (47.5)	0.359	14 (38.9)	15 (60.0)	0.104
Subscapularis tendonitis	6 (16.7)	4 (10.5)	0.510	0 (0)	10 (16.4)	0.193	6 (16.7)	4 (16.0)	>0.999
Capsulitis	6 (16.7)	4 (10.5)	0.510	0 (0)	10 (16.4)	0.193	6 (16.7)	4 (16.0)	>0.999
Subacromial impingement syndrome	2 (5.6)	1 (2.6)	0.610	0 (0)	3 (4.9)	>0.999	2 (5.6)	1 (4.0)	>0.999
Limited mobility	32 (88.9)	33 (86.8)	>0.999	11 (84.6)	54 (88.5)	0.654	32 (88.9)	22 (88.0)	>0.999
Arm in forward flexion	13 (36.1)	17 (44.7)	0.450	4 (30.8)	26 (42.6)	0.429	13 (36.1)	13 (52.0)	0.217
Other limitations of the shoulder	16 (44.4)	18 (47.4)	0.801	4 (30.8)	30 (49.2)	0.227	16 (44.4)	14 (56.0)	0.375
Age, yr	63.2 (10.8)	59.0 (10.5)	0.090	57.0 (10.7)	61.9 (10.7)	0.135	63.2 (10.8)	60.0 (10.4)	0.251

[a]Quantitative variables are described using mean(SD), and qualitative variables using absolute and relative frequencies.

[b]Withdrew from the study: intervention group, 0 (0); control group, 13 (34.2); completed the study: intervention group, 36 (100); control group, 25 (65.8). $P < 0.001$.

TABLE 3. Effectiveness of our intervention in the patients

Variable	Intervention Group (n = 36)	Control Group (n = 25)	Difference, Mean (95% CI)	P
Constant-Murley	−15.7 (6.8)	−11.6 (11.6)	−4.1 (−8.8 to 0.6)	0.085
QuickDASH	26.3 (14.3)	11.6 (11.9)	14.7 (7.7 to 21.7)	<0.001
VAS	3.0 (1.4)	3.1 (1.8)	−0.1 (−1.0 to 0.7)	0.723

Variables are described using mean(SD) or mean (95% CI).
CI, confidence interval.

Table 3 shows the resulting benefit of the intervention using the tests analyzed. The VAS results showed no significant differences with almost no benefit (difference = −0.1, P = 0.723). The Constant-Murley test revealed differences of 4.1 points in favor of the intervention, very close to significance (P = 0.085). Finally, the QuickDASH test showed significant differences (P < 0.001) with the patients in the intervention group scoring 14.7 points more improvement than the control group.

DISCUSSION

Summary

Our clinical trial concluded that conducting group physiotherapy in patients who experience nontraumatic inoperable shoulder pain produced a significant reduction in functional limitations (QuickDASH). There were no differences, however, in the VAS and Constant-Murley scores between the two groups. Finally, our intervention resulted in a decrease in the dropout rate in those who undertook physiotherapy treatment.

Strengths and Limitations of the Study

The main strength of our study is the novel assessment through a randomized controlled trial of the effectiveness of a group physiotherapy intervention in shoulder impingement syndrome because our literature search resulted in no such studies (Table 1).[5–12] The use of a randomized clinical trial minimized possible confounding and information and selection biases, because during the entire process, the two groups examined showed no statistically significant differences between them. Furthermore, to minimize information bias, all recommendations were followed for taking accurate measurements for the strength component of the Constant-Murley test.[29] On the other hand, we have to consider that the study population comprised patients with multiple conditions with a certain degree of heterogeneity in the diagnosis for which they were referred to our physiotherapy unit. Accordingly, it would be interesting to repeat the study focusing on each of the disorders independently, that is, undertaking a stratified analysis of the results. Finally, it is of note that no significant differences were found with the Constant-Murley test, because this test contemplates an objective measurement of shoulder muscle strength and movement. Nevertheless, our sample size was calculated according to the DASH, with a view to detecting significant differences in the measurements; thus, this sample size might be insufficient to detect differences with the Constant-Murley test. Using the results obtained in our study would require 77 patients per group to be able to find differences in the means of this test with a power of 80%. Given the difficulty to gather this number of patients in a single physiotherapy service (as seen in the sample sizes of the studies shown in Table 1),[5–12] this should be done with multicenter studies.

Comparison With the Existing Literature

We encountered difficulties when comparing our results with those obtained in other studies, because none of these conducted a group physiotherapy intervention (Table 1).[5–12] Furthermore, these studies did not compare the differences in improvement using the QuickDASH, VAS, and Constant-Murley scores between the groups examined (intervention or control), because they only analyzed the final status of the patients. For this reason, we calculated the improvement in each group and we determined the differences between the absolute values for each technique, which is the value that will help us compare our results. With respect to improvement on the VAS in our study, there was almost none when compared with the control group and this was not statistically significant, whereas the VAS in the other studies had an improvement ranging from 0.09 to 1.69 points on the scale. In the Constant-Murley, we obtained a difference of 4.1 points in favor of the intervention group, close to significance (P = 0.085). This value was between 0.58 and 12.05 in the other studies, with a median difference in improvement of 3.03; that is, our study obtained results above the median values obtained by others. The most significant improvement was obtained using the QuickDASH, with a total of 14.7 points, very similar to the maximum obtained by others (15.42 points) and well above the minimum of these (3.06 points) (Table 1).[5–12]

Although others have obtained better results in some of the measures analyzed (Table 1),[5–12] we must emphasize that the interventions they designed require special equipment and personnel for their implementation. They involve an additional cost for their implementation. Our intervention, like all those designed by the other authors (Table 1),[5–12] requires only one physical therapist who supervises physiotherapy exercises, which are performed at the same time by all the patients, reducing the time needed to implement the intervention. This does not occur with the other techniques, where the physical therapist must dedicate one-on-one time with each patient, thereby increasing the associated costs.

The analysis of losses to follow-up found no losses in the intervention group. This was possibly due to the patients being more motivated when doing the exercises in a group

and supervised by a physical therapist, because performing them at home could lead to lack of adherence, mainly from forgetfulness.

Implications to Research and Clinical Practice

Having found significant differences in the QuickDASH, it is of interest that no differences in improvement were found between the two groups using the VAS and Constant-Murley scores. Nevertheless, the results found with the Constant-Murley test were very nearly significant ($P = 0.085$), giving mean differences of 4.1 points, which indicates that the intervention could improve shoulder function in our patients. As mentioned in the limitations section, confirming this improvement would require a sample size more than twice that of our study, as the number of patients in our study was calculated according to the DASH and not the Constant-Murley or the VAS. Applying the same criteria to calculate the sample size necessary to detect differences using the VAS gives more than 4000 patients. Added to which, the results would hardly be relevant for clinical practice because the question is totally subjective and the difference found was 0.1 points, equivalent to 1% of the total for the scale (maximum 10 points). After this analysis of the results, we can claim that our intervention seems to help the patients improve, although larger studies are needed to confirm the results and thus implement the exercise guide in physiotherapy services elsewhere.

This study has shown good results, and the exercises, described in detail, can be easily followed by any patient. We would, therefore, like to encourage other clinicians to follow our guide for stable nontraumatic, inoperable painful shoulder.

The implications for clinical practice include a much lower dropout rate, reduced costs, reduced waiting time from diagnosis to physiotherapy, and improvement in the QuickDASH. Given these results when performing the exercises in a group setting, our hospital has implemented the model followed in the intervention group in the protocol for treatment of shoulder impingement syndrome.

A study, which might help us better understand the benefits of the different methods of therapeutic exercise in patients with shoulder impingement syndrome, would be to compare the group physiotherapy exercise program with a one-on-one patient physiotherapy exercise program. If both treatment arms improve significantly, then it could be the supervised physiotherapy, that is, the effective clinical ingredient. If the group exercise arm improves significantly compared with the one-on-one exercise arm, then the value of the group effect could be more clearly supported.

ACKNOWLEDGMENTS

The authors thank Maria Repice and Ian Johnstone for their contribution to the translation of the text. The authors also thank the Rehabilitation Unit at San Juan de Alicante University Hospital for their input, which has improved the text. In addition, the authors thank Nadia Snacel for her support in the development of the physiotherapy guide. Finally, the authors thank professors Sergio Hernández-Sánchez and Carlos Lozano-Quijada from Miguel Hernández University.

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