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Contribution of Dry Needling to Individualized Physical Therapy Treatment of Shoulder Pain: A Randomized Clinical Trial

The prevalence of shoulder pain in primary care is quite high, with almost half of the general population consulting physicians at least once due to shoulder pain.[7,20] It is the third most common cause of musculoskeletal-related primary care consultations.[4,5] Shoulder pain may continue for 1 year or more in 60% of cases,[32] and in 65% of these cases it requires regular pharmacological treatment over extended periods.[20] Extracapsular soft tissue is believed to be implicated in over 90% of shoulder pain cases.[16] The most prevalent extracapsular soft tissue lesions, both in active and nonactive populations, are disorders of the rotator cuff[50] (RC) and related tissues[54] associated with subacromial impingement syndrome (SIS).[6,8,59]

STUDY DESIGN: Multicenter, parallel randomized clinical trial.

BACKGROUND: Myofascial trigger points (MTrPs) are implicated in shoulder pain and functional limitations. An intervention intended to treat MTrPs is dry needling.

OBJECTIVES: To investigate the effectiveness of dry needling in addition to evidence-based personalized physical therapy treatment in the treatment of shoulder pain.

METHODS: One hundred twenty patients with nonspecific shoulder pain were randomly allocated into 2 parallel groups: (1) personalized, evidence-based physical therapy treatment; and (2) trigger point dry needling in addition to personalized, evidence-based physical therapy treatment. Patients were assessed at baseline, posttreatment, and 3-month follow-up. The primary outcome measure was pain assessed by a visual analog scale at 3 months, and secondary variables were joint range-of-motion limitations, Constant-Murley score for pain and function, and number of active MTrPs. Clinical efficacy was assessed using intention-to-treat analysis.

RESULTS: Of the 120 enrolled patients, 63 were randomly assigned to the control group and 57 to the intervention group. There were no significant differences in outcome between the 2 treatment groups. Both groups showed improvement over time.

CONCLUSION: Dry needling did not offer benefits in addition to personalized, evidence-based physical therapy treatment for patients with nonspecific shoulder pain.

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KEY WORDS: *dry needling, myofascial trigger points, personalized physical therapy treatment*

Some studies[4,27] have suggested the existence of myofascial trigger points (MTrPs) as one of the causal agents of shoulder pain and functional limitations. Despite the extensive literature on the role of trigger points,[9,19,22,23,41,61,62,65] the appropriate diagnostic criteria[5] and, indeed, their very existence remain controversial.[51,52] As there is no test to objectively confirm their existence, their diagnosis is exclusively clinical.[61,64] Although there is a lack of knowledge regarding the specific mechanisms involved in the clinical phenomenon of trigger points, a trigger point is considered to be a hypersensitive spot in taut

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bands of skeletal muscle that is painful upon stimulation and that elicits referred pain.[41,64]

There are diverse physiotherapeutic treatments available for the treatment of shoulder pain.[26] Some studies have highlighted the prevalence of MTrPs in different pathologies of the shoulder.[3,4,27,30,33] Trigger point dry needling has become recognized as an intervention targeting the treatment of MTrPs.[25,41,49] The objective of the dry needling intervention (repeated needle insertion) is to deactivate (remove the peripheral source of persistent nociceptive input) the trigger point via mechanical interruption as a region accumulating multiple sensitized nociceptors,[18] after initially causing a local twitch response.[60,64] Insertion of a needle into the skin and subcutaneous cell layer leads to responses provoked by the very needle insertion,[12] which activates pain control responses at the level of the posterior horn of the spinal cord[49] (also obtained by superficial needling,[1] another method described for the treatment of myofascial pain). Assuming that a local twitch response is obtained,[31] the mechanical effect as therapy is achieved through connective tissue remodeling, plasticity, and decrease of inflammatory mediators on the MTrP to interrupt its pathogenic mechanisms.[60] There is no evidence to suggest an increase in effectiveness with the injection of substances such as local anesthetics in MTrPs,[14] as compared to needling with no substance.[58] Clinical trials that have been conducted on subjects with shoulder pain up until now have used conservative techniques and compared the results with those from a control group (a wait-and-see approach or a placebo intervention).[4,27]

The aim of this study was to investigate the effectiveness of dry needling in addition to personalized, evidence-based physical therapy treatment versus personalized, evidence-based physical therapy treatment alone in the treatment of nonspecific shoulder pain.

METHODS

Design Overview

The study design was that of a multicenter, randomized clinical trial, with a follow-up of 3 months following treatment completion. The participants were randomized into 2 parallel groups: a control group that received personalized, evidence-based physical therapy treatment, and an intervention group that received, in addition to the personalized treatment, MTrP dry needling.

As a randomized clinical trial, the current study was performed in accordance with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT),[21] which recommends the inclusion of a set of core outcome domains in clinical trials of pain treatments. The recommendations established by the Consolidated Standards of Reporting Trials (CONSORT) statement[10,46] for randomized controlled trials were also followed. The trial was retrospectively registered in February 2009 with the ISRCTN registry (ISRCTN30907460). Participant recruitment took place from October 2008 to August 2010. The protocol of this study was published July 2009.[48] Modifications were made to the protocol in terms of the number of sessions held, so that the treatment provided would reflect as closely as possible to routine clinical practice in the physical therapy departments of primary care centers. The sample size was decreased from that published in the protocol, due to a recalculation based on the effectiveness of studies with conservative techniques that were published after the publication of the original protocol.[3] Also, additional outcome measures were included.

Setting and Participants

Patients with shoulder pain who visited a general practitioner in any of 5 primary health care centers in Zaragoza, Spain were recruited for inclusion in the study. Potential participants who provided informed consent to participate in the study were considered eligible if they met the following selection criteria: aged 18 years or older, having nonspecific shoulder pain considered by the general practitioner to be consistent with RC tendinopathy or SIS, and having a range of movement greater than 50% (90°) of full range (180°) of flexion, abduction, or scapular plane elevation.

Patients who presented with the clinical symptoms of nonspecific shoulder pain that were consistent with clinically suspected RC tendinopathy or SIS were included. However, 91% of the sample underwent a diagnostic imaging test (ultrasound) and 50% underwent magnetic resonance imaging (MRI) to confirm their eligibility to participate.

The exclusion criteria were prior surgery for subacromial syndrome; disability, pain, or sudden loss of strength after an injury that suggested another condition; glenohumeral instability; symptoms that suggested a systemic disease; impossibility of attending intervention sessions or refusal to participate; and, in the researcher's judgment, any illness or condition that might interfere with trial completion, or harm to the patient that could result from participation.

The participants provided informed consent before they were aware of their group assignment and before they were assessed. Before giving their consent, patients were offered a general overview of the aims and characteristics of the study and interventions. They were informed that they would be participating voluntarily and that they could withdraw at any time, with the guarantee that they would continue to receive the treatment considered most appropriate by their doctor. Data collection involved no risk to the participants. A patient was considered to have withdrawn from the trial if he or she withdrew informed consent, the researcher felt that he or she should withdraw from the study for safety reasons, or the researcher felt it to be in the best interest of the patient.

The study was conducted in accordance with Helsinki Declaration norms. The study protocol was approved by the

Clinical Research Ethics Committee of Aragón (01/2008).

Role of the Funding Source

The study was funded by a grant from the Spanish Government's Ministry of Health (grant number PI07/90924). The role of the financing source was to verify that the study was conducted as requested and in compliance with regulations for research and public funding, as well as with legislation regarding ethical aspects in the study implementation.

Sample Size

Sample-size calculation was based on the clinically important improvement of 1.5 points on a 0-to-10 visual analog scale (VAS) for pain,[37] with a standard deviation of 2 points. Assuming a 95% confidence interval and power of 90%, the resulting sample size was 38 participants per group, for a total of 76 individuals. The estimated attrition rate, based on previous studies, was 10%; therefore, the required number of patients for recruitment was 86. With an aim to exceed this number, 132 subjects (66 randomized in each treatment group) were recruited to ensure the reliability of the study.[48] The protocol did not include any interim analyses or stopping rules.

Randomization

Patients were referred to physical therapy by general practitioners of primary care centers, and screened for inclusion and exclusion by physical therapists from the involved physical therapy units.

Participants were assigned to 1 of the 2 groups using a computer-generated random number sequence with no restrictions. The information for the random allocation sequence was implemented by phone from an independent researcher, who stated the type of treatment assigned for each new patient. The sequence was concealed throughout the study. Group assignment was carried out by the independent researcher.

Due to the nature of the study, it was impossible to maintain blinding of both the physical therapist and patient. All of the assessments were performed by an evaluator blinded to group allocation.

Interventions

The interventions were as follows. Participants in the control group underwent a clinical examination process by the treating physical therapist, beginning with a thorough background history and followed by a physical examination of the shoulder girdle[43,56,57] and shoulder joints.[36] All joints were manually assessed with active movements and a translation test in accordance with Kaltenborn therapy[36] (**APPENDIX A**, available at www.jospt.org). Personalized physical therapy treatment was based on the most appropriate manual therapy techniques after physical evaluation of the patient: articular gliding or restoration of the glenohumeral[36] and scapulothoracic[43] translational joint movement, stretching of the shortened peri-articular muscle tissue directly or indirectly involved in the shoulder joint movement,[56,57] isometric exercises, exercises for proprioceptive re-education and scapular control,[43,47] range-of-motion stretching at home, and postural recommendations for everyday activities[24,26,28,56] (**APPENDIX A**, and illustrated in 6 videos available at www.jospt.org). These techniques were applied in an individualized manner, based on the patient's condition.[39,40] The research group attended training sessions to standardize the treatment protocol and received a written procedural manual, in which the applied techniques, number of sessions, and their contents were recorded (**APPENDIX A**). The patients were provided 10 personalized physical therapy treatment sessions, each lasting 30 minutes and distributed twice weekly.

Participants assigned to the intervention group received the physical therapy treatment described above, as well as dry needling of active MTrPs identified by the treating physical therapists in the participants' supraspinatus, infraspinatus, subscapularis (medial, lateral superior, and lateral inferior), teres minor, and deltoid (anterior, medial, and posterior) muscles. Needling was performed using the Hong technique[31] ("fast in, fast out"), accompanied by the subsequent application of cold spray to diminish any pain sensation after needling.[44,64] Acupuncture needles measuring 0.25 × 25 mm, 0.30 × 50 mm, and 0.30 × 75 mm, with a guide tube, were used. A total of 3 needling sessions were conducted, distributed over the first, fourth, and seventh sessions, respectively, in order to have 8 days between each dry needling[17] and needling of the active MTrPs once in each session.

Outcome Measures

Baseline Assessment Sociodemographic variables were collected at baseline (age, sex, and occupation), as well as history of pain, timing of clinical evolution, background history, prior treatments, and medication (drug type, time administered, and evolution with medication).

Primary Outcome Variable The primary outcome variable was patient-reported pain on the pain VAS. The pain VAS was designed to permit a thorough and understandable subjective assessment of pain. The pain VAS consists of a 10-cm horizontal line, with marks at both ends to define the limits of the pain experience as "no pain" (0) and "maximum pain experienced" (10), with higher scores indicating greater pain. Patients were asked to evaluate the overall pain experienced that caused them to seek treatment. The psychometric usefulness of the VAS for pain measurement has been widely demonstrated.[63] Clinically important improvement on the pain VAS is considered to be 1.5 points.[37]

Secondary Outcome Variables Secondary outcome variables were joint range-of-motion limitations, Constant-Murley score for pain and function, and number of active MTrPs. Active articular limitation of the glenohumeral joint was measured in degrees, using a digital inclinometer (Acumar Digital Inclinometer; Lafayette Instrument Company, Lafayette, IN) for flexion and abduction motion. For internal and external rotation,

a subscale of the functional Constant-Murley score was used to determine rotation based on functional movement (**APPENDIX A**).

Function was measured with the Constant-Murley score,[2,38] which ranges from 0 to 100 and includes subscales for subjective pain (0-15 points), everyday activities (0-20 points), and objective subscales on mobility (40 points) and strength (25 points), with higher scores indicating greater functionality. The Constant-Murley score has been shown to have good reliability[13,55] and is one of the most frequently used measures in clinics.[13,55]

The supraspinatus, infraspinatus, subscapularis (medial, lateral superior, and lateral inferior), teres minor, and deltoid (anterior, medial, and posterior) muscles were evaluated for the existence of active MTrPs. All of these localizations were based on the nomenclature and localization of Travell and Simons.[64] Diagnosis was made according to updated Travell and Simons[4] diagnostic criteria: the presence of a hypersensitive spot in a palpable taut band, a palpable or visible local twitch response on palpatory stimulus, and reproduction of referred pain elicited by palpation.[41,64]

Additional Outcomes One additional outcome measure not specified in the trial registration or published protocol was added: nocturnal pain, self-reported as yes/no.

Assessment Periods

Patients were assessed at 3 time points: baseline, posttreatment, and 3 months. Follow-up assessments (posttreatment and 3 months) were conducted by an evaluator blinded to group allocation. The treating physical therapists, as well as the evaluators, were physical therapists with over 5 years of experience in physical therapy diagnosis and treatment, including the treatment of MTrPs. They also underwent an additional 4 sessions of protocol standardization with an expert in dry needling treatment. Furthermore, they were provided with a telephone contact to make any necessary consultations regarding doubts or incidents that may arise during the study period.

Statistical Analysis

Clinical efficacy was assessed using intention-to-treat analysis. The worst-observation-carried-forward method was used to handle missing data. Baseline comparison of key variables was made between the groups after randomization to establish baseline comparability. For each group, the improvement at the end of the treatment and 3 months later was analyzed using a paired-samples t test for quantitative variables. McNemar's test was used for analysis of the binary outcome (yes/no) of nocturnal pain. Differences between both groups at the end of the treatment and 3 months later were analyzed using analysis of covariance. Thus, for the primary outcome variable and for each prespecified secondary outcome variable at each time point (posttreatment and 3 months), we adjusted a linear model in which treatment type and corresponding outcome measure at baseline were the independent variables. For nocturnal pain, in order to compare between groups, we considered the patients whose nocturnal pain had improved (changed from yes to no) and those whose nocturnal pain did not change or got worse (changed from no to yes). The frequencies of these categories between groups were compared using the chi-square test at posttreatment and 3 months.

Statistical analyses were performed with SPSS Version 22.0 (IBM Corporation, Armonk, NY), and P values below .05 were considered to be statistically significant.

RESULTS

Participant Flow and Compliance

The **FIGURE** illustrates the flow of participants during the trial. Between October 2008 and August 2010, 142 patients with pain and shoulder limitations were assessed for inclusion in the study, 22 of whom were excluded. Of the 120 patients included in the study, 57 were randomly assigned to the dry needling group and 63 to the control group. All patients received the allocated intervention, and all were analyzed using intention-to-treat analyses. Of the 120 subjects who began the study, 117 (97.5%) completed the treatment, and 109 (90.8%) participated in the 3-month follow-up. The attrition rate was similar between the 2 treatment groups: 2 out of 63 (3.17%) patients in the personalized treatment group and 1 out of 57 (1.75%) patients in the personalized treatment-plus-dry needling group dropped out of the study over the 10 treatment sessions. By the 3-month follow-up, the total attrition rate was 11 out of 120 participants: 6 out of 63 (9.52%) in the personalized treatment group and 5 out of 57 (8.77%) in the personalized treatment-plus-dry needling group. Due to the low dropout rate, predictors of dropout were exempt from further analysis, and the worst-observation-carried-forward method was considered adequate to deal with missing data for the intention-to-treat analysis.

Group Baseline Characteristics

TABLE 1 displays the baseline characteristics of the 2 study groups. There were no important differences between groups in any of the sociodemographic or clinical variables, nor in the diagnosed pathology via ultrasound/MRI, indicating that the 2 groups were equivalent with regard to the measured variables.

Primary Outcome Variable

TABLE 2 displays the data for the assessment of the principal and secondary variables at baseline, posttreatment, and 3-month follow-up for the personalized treatment and personalized treatment-plus-dry needling groups. Participants in both groups showed significant improvement at the end of the treatment period and at the 3-month follow-up. The patients assigned to the personalized treatment-plus-dry needling group showed a slight improvement (difference estimate, 0.86; confidence inter-

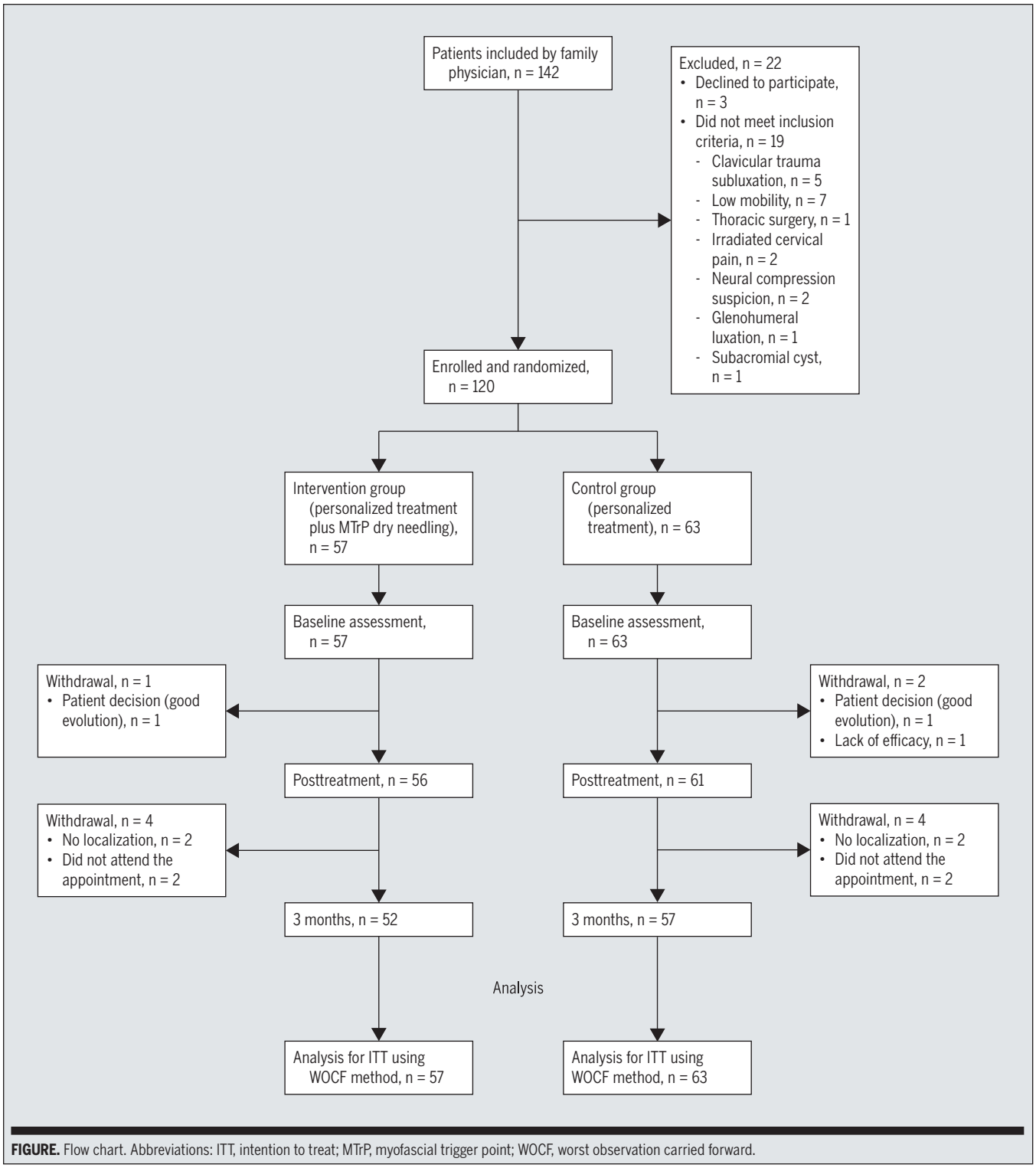

FIGURE. Flow chart. Abbreviations: ITT, intention to treat; MTrP, myofascial trigger point; WOCF, worst observation carried forward.

val: 0.06, 1.67) in pain at the end of the treatment period, whereas this difference was not apparent at the 3-month follow-up.

Secondary and Additional Outcomes

Participants in both groups showed significant improvement at the end of the treatment period and after 3 months in regard to internal rotation range of motion, functionality, and number of active trigger points. The patients assigned to the personalized treatment group showed

TABLE 1 Baseline Sociodemographic and Clinical Characteristics of the Sample (n = 120)

Variable	Personalized Treatment (n = 63)	Personalized Treatment Plus Dry Needling (n = 57)
Sociodemographic variables		
Sex, n		
Male	28	17
Female	35	40
Age, y*	54.32 ± 11.45	52.74 ± 11.81
Pain (VAS)*	6.75 ± 1.5	6.58 ± 1.52
Glenohumeral active ROM, deg*		
Flexion	136.09 ± 16.42	135.97 ± 20.40
Abduction	141.74 ± 27.87	150.02 ± 26.03
External rotation	7.08 ± 2.96	7.82 ± 2.46
Internal rotation	6.37 ± 2.67	6.21 ± 2.71
Functionality (Constant-Murley score)*	47.6 ± 11.53	50.3 ± 11.75
Nocturnal pain, n		
No	22	16
Yes	41	41
Number of active trigger points*	4.82 ± 1.75	5.07 ± 1.86
Pathology, n		
Total/partial tear		
No	51	48
Yes	6	4
Tendinopathy		
No	37	39
Yes	20	13
Arthrosis		
No	35	38
Yes	22	14
Bursitis		
No	43	46
Yes	14	6
Injury		
No	23	27
Yes	34	25

Abbreviations: ROM, range of motion; VAS, visual analog scale.
**Values are mean ± SD.*

improvement in external rotation range of motion, whereas this difference was not apparent in the personalized treatment-plus-dry needling group. Comparing both groups, similar effects were found between the 2 treatments for all prespecified secondary outcome variables at the end of the treatment period and at 3-month follow-up.

Results for the additional variable not specified a priori are reported in **APPENDIX B** (available at www.jospt.org). A change in nocturnal pain (from yes at baseline to no after treatment) indicated improvement in nocturnal pain in both groups following treatment and at the 3-month follow-up. The results indicated a slight between-group difference in nocturnal pain improvement at posttreatment favoring the personalized treatment-plus-dry needling group (odds ratio = 0.41; confidence interval, 0.17, 0.99), but not at 3-month follow-up.

DISCUSSION

This is the first clinical trial to assess the effectiveness of dry needling when added to a personalized treatment of shoulder pain, compared with that of personalized treatment alone. There were no clinically or statistically significant differences between the intervention groups, in terms of pain, range of motion, function, or number of MTrPs at 3-month follow-up. The only statistically significant difference found at posttreatment was in pain, as indicated by a difference estimate of 0.86 and a confidence interval of 0.06 to 1.67 on the pain VAS. This, according to an a priori defined minimum difference of 1.5 on the pain VAS, is not a clinically relevant improvement.

The improvement in pain reported within both treatment groups was clinically relevant, with a decrease in pain VAS score at posttreatment of more than 2 points[37] and at 3 months of more than 3 points. We are unable to attribute this improvement in pain to the treatments, given that our study lacked a control group; however, it has been shown in a controlled study by Kachingwe et al[35] that manual therapy may, with or without supervised exercises, be superior to physician advice, and in a controlled study by Dickens et al[15] that it may be superior to no intervention. Nevertheless, a study with a control group is recommended to confirm these results.

As for function, changes in the total Constant-Murley score,[29] although statistically significant, did not exceed the minimum clinically important change of 17 points in either of the 2 treatments. Virtually no changes in range of motion were observed. Significant improvement in internal rotation was similar for both groups, and significant improvement in external rotation was observed in the group that received personalized treatment alone. It is possible that there was

TABLE 2 Outcome Data at Baseline, Posttreatment, and 3-Month Follow-up*

	Personalized Treatment	Personalized Treatment Plus Dry Needling	Between-Group Differences†
Pain (VAS)			
Baseline	6.75 ± 1.50	6.58 ± 1.52	
Posttreatment	4.71 ± 2.28	3.81 ± 2.20	0.86 (0.06, 1.67)
3 mo	3.59 ± 2.61	3.00 ± 2.44	0.52 (−0.37, 1.42)
Within-group improvement from baseline‡			
Posttreatment	2.04 (1.44, 2.63)§	2.77 (2.08, 3.46)§	
After 3 mo	3.16 (2.55, 3.77)§	3.58 (2.82, 4.34)§	
Glenohumeral active ROM, deg			
Flexion			
Baseline	136.09 ± 16.42	135.97 ± 20.40	
Posttreatment	136.17 ± 18.90	140.53 ± 15.47	4.41 (−1.29, 10.10)
After 3 mo	141.08 ± 16.49	139.32 ± 17.61	−1.71 (−7.34, 3.92)
Within-group improvement from baseline‡			
Posttreatment	0.08 (−4.58, 4.75)	4.56 (−0.67, 9.79)	
After 3 mo	4.99 (0.44, 9.53)	3.35 (−2.06, 8.77)	
Abduction			
Baseline	141.74 ± 27.87	150.02 ± 26.03	
Posttreatment	149.23 ± 25.18	151.17 ± 25.64	−0.98 (−9.64, 7.68)
3 mo	148.12 ± 25.65	149.89 ± 25.18	−0.60 (−9.51, 8.31)
Within-group improvement from baseline‡			
Posttreatment	7.49 (−0.02, 14.99)	1.15 (−6.48, 8.79)	
After 3 mo	6.37 (−1.34, 14.09)	−0.13 (−8.43, 8.17)	
External rotation			
Baseline	7.08 ± 2.96	7.82 ± 2.46	
Posttreatment	8.44 ± 2.20	8.53 ± 2.31	−0.09 (−0.89, 0.69)
3 mo	8.54 ± 2.52	8.53 ± 2.41	−0.24 (−1.09, 0.62)
Within-group improvement from baseline‡			
Posttreatment	1.36 (0.64, 2.09)§	0.70 (−0.12, 1.53)	
After 3 mo	1.46 (0.75, 2.17)§	0.70 (−0.15, 1.55)	
Internal rotation			
Baseline	6.37 ± 2.67	6.21 ± 2.71	
Posttreatment	7.21 ± 2.86	7.86 ± 2.13	0.74 (0.02, 1.46)
3 mo	7.73 ± 2.37	8.00 ± 2.14	0.34 (−0.36, 1.04)
Within-group improvement from baseline‡			
Posttreatment	0.84 (0.33, 1.35)‖	1.65 (0.99, 2.31)§	
After 3 mo	1.36 (0.75, 1.98)§	1.79 (1.14, 2.44)§	

Table continues on page 18.

little capacity for improvement in range of motion, given that the limitations in range of motion, in general, were not very high (mean flexion and abduction ranges were over 75%, external rotation range was over 70%, and internal rotation was over 60% of overall movement). These results are consistent with those from other studies in which manual therapy was assessed for shoulder pain,[34] which found few and varied changes in range of motion,[11] and increases that may be related to the initial level of restriction[42] and the range in which the joint movement was carried out.[11]

We chose to use a nonstandardized physical therapy treatment protocol in both groups, because physical therapists generally use a multimodal treatment approach.[26] Manual therapy, stretching, and proprioceptive re-education and control exercises have also been described to deactivate MTrPs.[41,53,64] The reason for the similar decrease in MTrPs between both groups in our study may be that the manual therapy indirectly improved the MTrPs. The treatment of shoulder pain

TABLE 2 Outcome Data at Baseline, Posttreatment, and 3-Month Follow-up* (continued)

	Personalized Treatment	Personalized Treatment Plus Dry Needling	Between-Group Differences†
Functionality (Constant-Murley score)			
Baseline	47.39 ± 11.53	50.30 ± 11.75	
Posttreatment	57.29 ± 13.74	61.44 ± 12.00	3.04 (−1.36, 7.44)
3 mo	61.77 ± 16.18	62.89 ± 12.91	−0.07 (−5.19, 5.04)
Within-group improvement from baseline¶			
Posttreatment	9.68 (6.55, 12.81)§	11.14 (7.10, 15.18)§	
After 3 mo	14.39 (10.55, 18.22)§	12.60 (8.36, 16.83)§	
Number of active trigger points			
Baseline	4.82 ± 1.75	5.07 ± 1.86	
Posttreatment	3.97 ± 1.71	4.17 ± 2.01	−0.001 (−0.39, 0.38)
3 mo	3.75 ± 1.94	4.05 ± 2.12	0.10 (−0.39, 0.59)
Within-group improvement from baseline‡			
Posttreatment	0.86 (0.61, 1.10)§	0.89 (0.57, 1.21)§	
3 mo	1.08 (0.73, 1.43)§	1.02 (0.65, 1.38)§	

Abbreviations: ROM, range of motion; VAS, visual analog scale.
**Values are mean ± SD unless otherwise indicated.*
†Values are mean difference (95% confidence interval) between both treatments by using analysis of covariance (outcome score at different time points is the dependent variable and the corresponding variable at baseline is the covariable).
‡Values are mean difference (95% confidence interval). Improvement calculated as the reduction of the variable.
§Statistically significant difference (P<.001).
‖Statistically significant difference (P<.01).
¶Values are mean difference (95% confidence interval). Improvement calculated as the increment of the variable.

through the inactivation of MTrPs has been previously studied by Bron et al[3] and Hains et al,[27] who found significant improvements in pain and function following conservative treatment as compared to a control group, thereby associating the improvement with the treatment of the MTrPs.

With respect to the nocturnal pain variable, our study found that the number of participants with improved nocturnal pain was slightly higher in the dry needling group after treatment. This comparison showed an odds ratio of 0.41, with a confidence interval (0.17, 0.99) that did not reveal important differences with respect to this variable. Moreover, we are unable to assess the clinical meaningfulness of this small improvement due to the nature of the variable used (yes/no), and no significant difference existed at 3-month follow-up. This outcome was not a primary or secondary outcome for this study, and therefore should not be considered of consequence; it might have been a chance finding, given that no other outcomes showed important significant differences.

The main strength of this study is that it is the first clinical study to assess the effectiveness of dry needling when added to personalized physical therapy treatment in primary care, with appropriate sample size and representativeness. Furthermore, a follow-up at 3 months following treatment completion provided an opportunity to analyze patient evolution after treatment. There are, however, several limitations to this study. One of these is the inclusion criterion of a diagnosis by a primary care physician based on clinical symptoms (although a large percentage of the subjects had their pathology confirmed via ultrasound or MRI). Finally, the follow-up period may be considered rather short; longer follow-up periods may be necessary to confirm the long-term stability of the improvements. Finally, although previous studies have shown that individualized manual therapy and exercise therapy may be superior to a no-treatment control,[15,35] larger, higher-quality studies are necessary to definitively establish the effectiveness of physical therapy management of nonspecific shoulder pain, RC disorders, or SIS.[11]

CONCLUSION

Dry needling as an adjunct to personalized treatment for shoulder pain provided no added benefits in terms of self-reported pain and function, range of motion, and reduction of active MTrPs. ◉

KEY POINTS

FINDINGS: Dry needling in addition to personalized physical therapy treatment did not provide added benefits in patients with nonspecific shoulder pain, with regard to self-reported pain and function, range of motion, and reduction of active MTrPs.

IMPLICATIONS: Dry needling is not justified as an adjunct to the management of shoulder pain by personalized, evidence-based physical therapy treatment.

CAUTION: In the primary care setting of this study, the inclusion of the participants was based on clinical diagnosis of nonspecific shoulder pain, as considered by a primary care physician to be consistent with RC tendinopathy or SIS and with impaired movement of less than 50% of the expected normal range of motion. Although a large percentage of the subjects had their pathology confirmed via ultrasound or MRI, the shoulder pain diagnosis was nonspecific. The evidence-based physical therapy treatment, although similar between the groups, was individualized and therefore not exactly replicable.

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PERSONALIZED TREATMENT

The following is a manual therapy treatment based on a kinesiopathological concept of Sahrmann,[56,57] where the altered patterns of movement are the origin of the structural lesions. It could be related to certain elements taken as the extrinsic factors of impingement syndrome and rotator tendinopathy, like scapular kinematics (dyskinesia), a tightness of the posterior joint capsule with anterior translation of the humeral head and the upmigration of the humeral head (up and ventral displacement). Within that concept, the lack of movement could cause a compensatory hypermobility in other structures. The purpose is to try to recover the right movement in the scapula and the humeral bones (joint gliding, keeping the rotation's instantaneous center) and to avoid other, further overloading, and secondarily it could help the muscles to work normal with less overload.

This trial is a pragmatic intervention of physical therapy in primary care and has been embedded in the normal daily process of delivery to primary care physical therapy units in Spain, where the general practitioners delivered the patient to the physical therapist in the same health center of primary care; they use the criteria for referral to those physical therapy units habitually (same criteria as inclusion criteria in the Methods section). The general practitioners did not have any specific training, but they had the criteria and all information about this work in a clinical session given by the physical therapists to the primary care team (general practitioners, nursing, pediatrics) of their health center to collaborate in this research work.

The physical therapist research team was composed of 7 physical therapists, working in primary care in the city of Zaragoza, Spain, and with more than 10 years of experience. They did not have the same background and specific training, but all of them had the experience working in manual therapy. However, there were several (3-4) training sessions prior to commencement of the study to guarantee uniform standardization in the procedure of the intervention (evaluation and treatment).

The first step was the assessment of the shoulder girdle in every patient, to identify the "clinical situation."

- Inspection: identification of the position of the scapula (up/low/upward rotation/downward rotation/protraction/anterior or posterior tilt)
- Active range of motion with digital inclinometer: flexion and abduction rotation measured with functional assessment from Constant-Murley score subscale (0-10)

Rotation	Points
Internal rotation	
Dorsum of hand to lateral thigh	0
Dorsum of hand to buttock	2
Dorsum of hand to lumbosacral junction	4
Dorsum of hand to waist (third lumbar vertebra)	6
Dorsum of hand to 12th dorsal vertebra	8
Dorsum of hand to interscapular region	10
External rotation	
Hand behind head with elbow held forward	2
Hand behind head with elbow held back	2
Hand on top of head with elbow held forward	2
Hand on top of head with elbow held back	2
Full elevation from on top of head	2
Total	10

- Joint-play assessment of glenohumeral joint: ventral, dorsal, inferior gliding in the sitting position

We used the techniques of manual therapy to obtain the objectives after evaluation. The objectives were (1) to recover the range of motion by restoring joint gliding in the glenohumeral (manual therapy 1 [MT1]) and scapulothoracic joints (manual therapy 2 [MT2]) and by stretching muscles in a shortened position (manual therapy 3 [MT3]), (2) to improve motor control by proprioception and stabilization exercises (manual therapy 4 [MT4]), and (3) to avoid recurrences by teaching the patient the previous exercises (manual therapy 5 [MT5]).

Clinical Reasoning for Choosing the Techniques

The physical therapist chose the most appropriate techniques to achieve the objectives above, depending on the identified clinical situation in the previous physical evaluation. This is a clinical-reasoning process in personalized treatment.

We use the dorsal gliding technique when we find a ventral position of the humeral head and a lack of dorsal gliding, and the glenohumeral inferior gliding technique for recovering inferior gliding in an up position of the humeral head and a lack of inferior gliding. In the case of a dorsal position of the humeral head and a lack of ventral gliding, we use glenohumeral ventral gliding.

The same clinical reasoning for the scapulothoracic joint is used: when the scapula is, for instance, in a downward-rotated position and there is a lack of upward rotation, we use upward-rotation scapulothoracic joint gliding. Following stretching, in the case of a downward-rotated position in the scapula, the muscles in the shortened position that should be stretched are the levator scapulae and rhomboid muscles.

In other cases of altered scapular position, stretching of the shortened muscles in relation to the altered scapular position would be different (for the up position: upper trapezius and levator scapulae; down position: lower trapezius and pectoralis major; upward rotation: upper trapezius, serratus

anterior, and lower trapezius; downward rotation: levator scapulae and rhomboid; anterior tilt: pectoralis minor, coracobrachialis, and short head of biceps brachii; retraction: medium trapezius and rhomboid; protraction: pectoralis major and minor). Stretching of the shortened muscles in relation to the anterior humeral head position is as follows: infraspinatus, teres minor, and posterior deltoid.

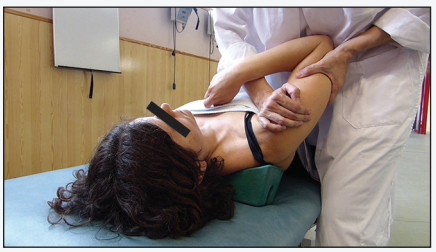
The proprioception and stabilization exercises are applied in all patients with whichever position scapular girdle, but tailored to each patient.

Manual Therapy of Physical Therapy Intervention (Including Exercises at Home)

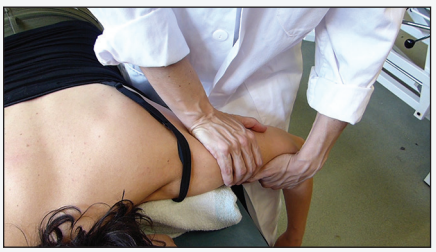
MT1: Gliding in the Glenohumeral Joint, Grade III

- To increase the diminished direction (posterior, inferior, anterior) in different positions at the limit of movement without pain (adjust position in flexion-abduction)
- To restore the correct joint play,[38] first in supine (from 0° to 90° of flexion-abduction, with a wedge support under the scapula where necessary) and a second time in a sitting position (relaxed position at 55° of flexion-abduction) (joint gliding mobilization video)

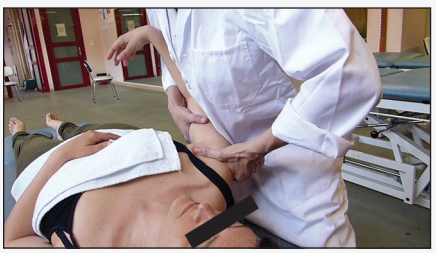
In the sitting position with the hands on the thighs, with a posterior position of the shoulder in relation to the elbow, the patient performs active correction, first with an exteroceptive stimulus in the posterior deltoid area, and then without any stimulus for posterior gliding; for inferior gliding, the patient performs active depression of the humeral head without depression of the global shoulder girdle. All exercises are performed in front of a mirror (joint gliding mobilization video).

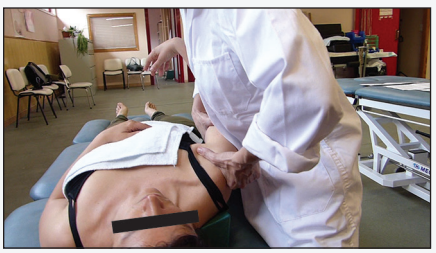


Dorsal glenohumeral joint gliding (joint gliding mobilization video)



Ventral glenohumeral joint gliding (joint gliding mobilization video)



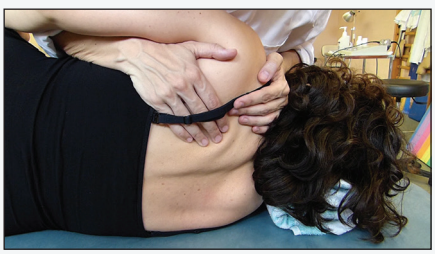


Caudal glenohumeral joint gliding (joint gliding mobilization video)

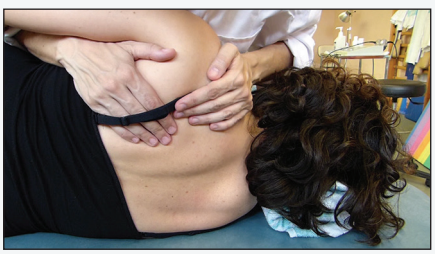
MT2: Gliding in the Scapulothoracic Joint Grade III and Correcting Scapular Posture

- Passive mobilization in the scapulothoracic joint (up/down, upward rotation, downward rotation, anterior tilt, protraction, retraction). Mobilizations to the opposite position[64] in lateral lying (joint gliding mobilization video)

The passive gliding techniques are the Kaltenborn grade III mobilizations; in the glenohumeral and scapulothoracic joints, they should be maintained for several seconds (approximately 1 minute), applying force after the slack of the joint and feeling the changes of tissue resistance; grade III is used to gain joint soft tissue elasticity. This maneuver could be repeated 2 to 3 times at the beginning of the first sessions to pass the active correction in the last sessions of treatment (schedule).



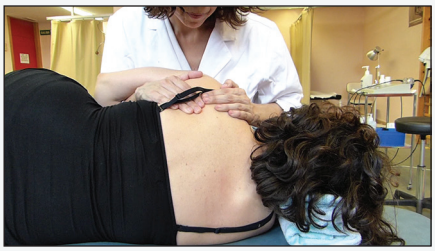
Superior scapulohumeral joint gliding (joint gliding mobilization video)



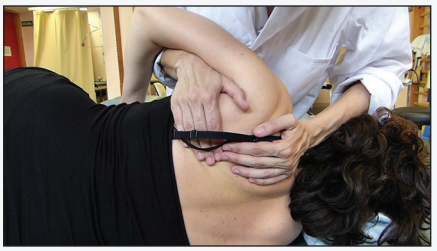
Inferior scapulohumeral joint gliding (joint gliding mobilization video)

Scapulohumeral adduction (retraction) (joint gliding mobilization video)

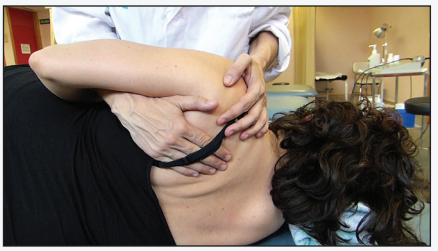
APPENDIX A



Scapulohumeral abduction (protraction) (joint gliding mobilization video)



Scapulohumeral upward rotation (joint gliding mobilization video)

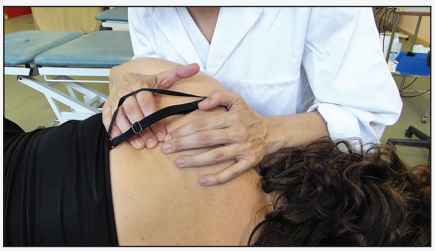


Scapulohumeral downward rotation (joint gliding mobilization video)

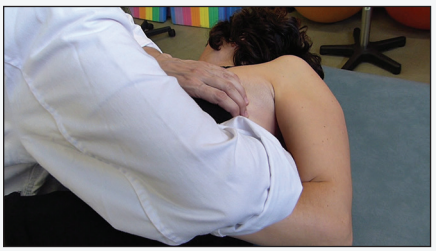
MT3: Stretching the Shortening Muscles Related to the Altered Scapular Position

- Up: upper trapezius and levator scapulae; down: lower trapezius, pectoralis major; upward rotation: upper trapezius, serratus anterior, and lower trapezius; downward rotation: levator scapulae and rhomboid; anterior tilt: pectoralis major, pectoralis minor, coracobrachialis, and short head of biceps; retraction: medium trapezius and rhomboid; protraction: pectoralis major and minor) (stretching 1 and stretching 2 videos)
- Stretching the shortened muscles in relation to the anterior humeral head position: infraspinatus, teres minor, and posterior deltoid (stretching 2 and self-stretching videos)

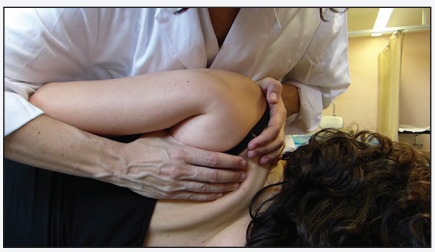
The stretching is associated with the respiratory cycles, increasing the movement of stretch (length) during exhalation and holding during inhalation, repeating 5 to 6 breaths in each stretch. One set of 2 to 3 stretches is performed for each muscle in each session, introducing and learning gradually the number of muscles (schedule). Learn all of these stretches to do at home (self-stretching video). The stretching is recommended once per day in the same manner. Not all muscles are stretched in all patients; the physical therapist must select the appropriate stretch in each case.



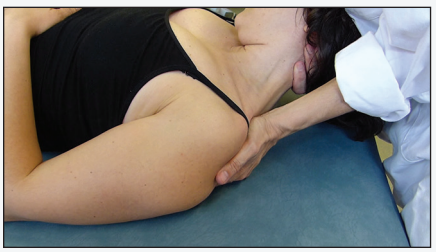
Passive middle trapezius and rhomboid muscle stretching (stretching 1 video)



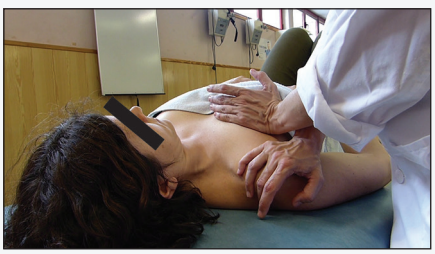
Passive serratus anterior muscle stretching (stretching 1 video)



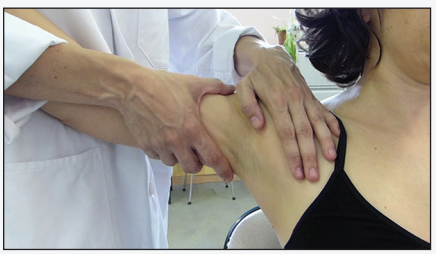
Passive lower trapezius muscle stretching (stretching 1 video)



Passive levator scapulae muscle stretching (stretching 1 video)



Passive pectoralis minor muscle stretching (stretching 2 video)



Passive pectoralis major muscle stretching (stretching 2 video)

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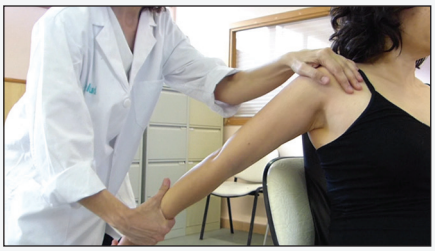
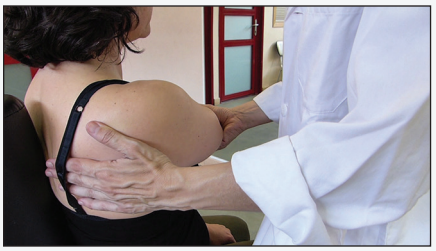


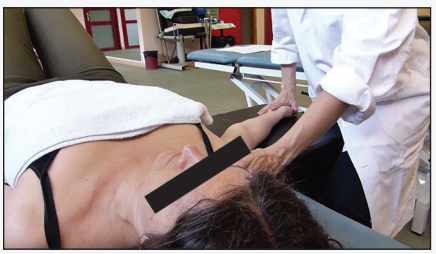
Passive biceps brachii and coracobrachialis muscle stretching (stretching 2 video)



Passive infraspinatus and teres minor muscle stretching (stretching 2 video)

MT4: Active Exercises of Proprioception and Stabilization in the Correct Humeral Position

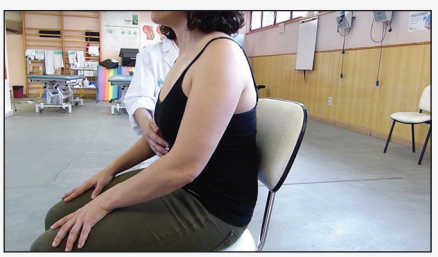
- Scapular relocation in supine: understand the asymmetries between shoulders in supine; with exteroceptive references from the bench, try to keep the symmetric position, avoiding the anterior tilt in this position specifically. To continue the correction, have the participant hold the position with breathing, insisting on breathing out and lowering the upper ribs. It is the easiest and the first performed exercise (stabilization and proprioception 1 video)



Scapular relocation exercise in supine (stabilization and proprioception 1 video)

- Scapular dissociation exercises: in the sitting position, move the scapula in different directions without moving the dorsal spine. Dissociate the scapular movement from the dorsal position/movement (stabilization and proprioception 2 video)

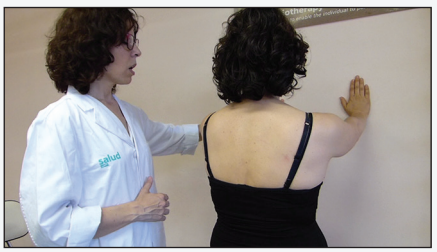
These exercises are explained in the first sessions; the progression is the commencement in supine, then seated, and finally proprioceptive and stabilization exercises with the patient in standing.



Scapular dissociation exercises (stabilization and proprioception 2 video)

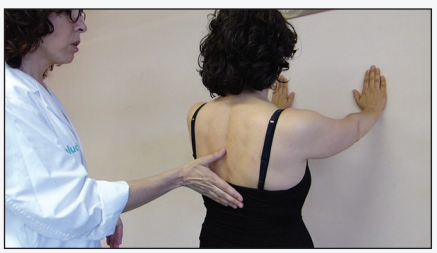
APPENDIX A

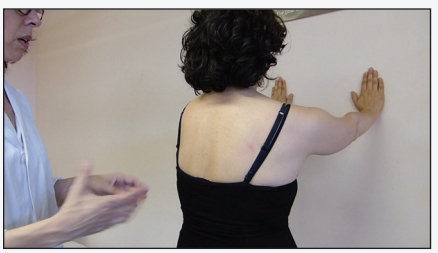
- Static scapular stabilization exercises: in the standing position in front of a wall with 90° of shoulder flexion, flat hands on the wall, pushing and pulling the hands without any associated movement in the scapula, especially winging (stabilization and proprioception 2 video)



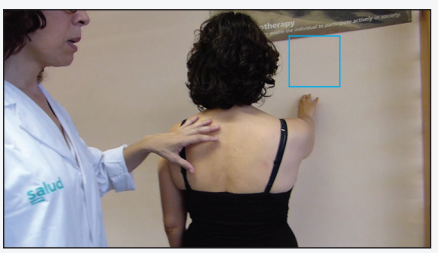
Static scapular stabilization (pushing and pulling) (stabilization and proprioception 2 video)

- Dynamic scapular stabilization exercises: the first exercise is to bring the body to the wall without moving the elbows, sliding the scapula (dissociation) without any associated movement (up, winging movement, etc). The second is to draw numbers or figures on a table, progressing to drawing on the wall, with humeral and scapular control (stabilization and proprioception 2 video)





Dynamic scapular stabilization exercises (scapular abduction/adduction) (stabilization and proprioception 2 video)

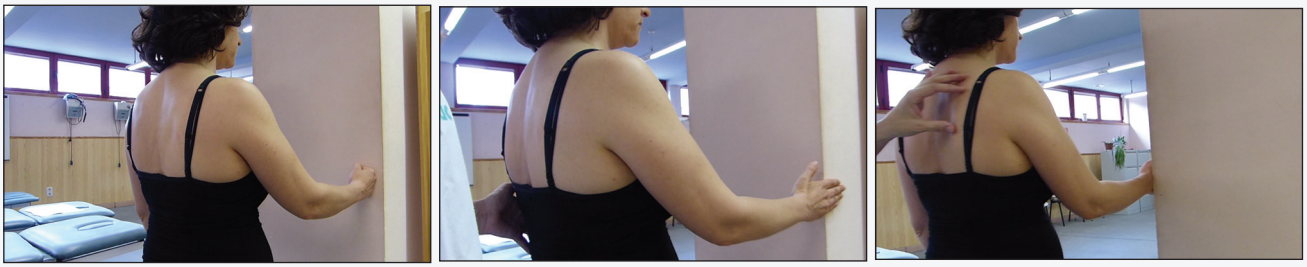


Dynamic scapular stabilization exercises (drawing figures) (stabilization and proprioception 2 video)

APPENDIX A

- Humeral stabilization: first in supine, with the correct scapular and humeral position, the patient makes drawings by hand in the air (the easiest and earliest exercise). The second exercise involves isometric contractions of the glenohumeral muscles, in the correct glenohumeral position, with resistance in the hand and elbow flexion. Be careful with the position and eventual pain (stabilization and proprioception 2 and 3 videos)

Dynamic humeral head stabilization exercises in supine (stabilization and proprioception 2 video)

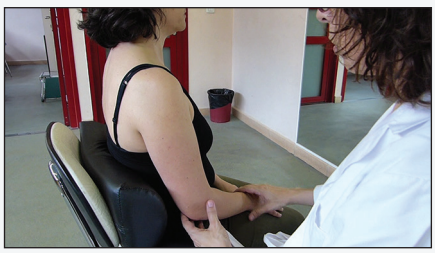


Static humeral head stabilization exercises (isometric contractions) (stabilization and proprioception 3 video)

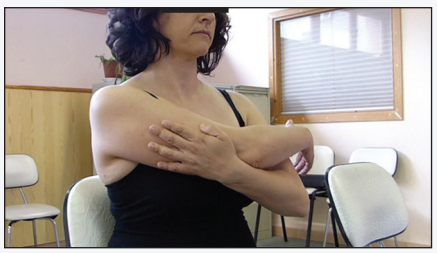
MT5: Recommendations for the Patient

- Exercises of active glenohumeral joint gliding (at the end of the joint gliding mobilization video), scapular dissociation (stabilization and proprioception 2 video), humeral stabilization (stabilization and proprioception 2 and 3 videos), static and dynamic stabilization (stabilization and proprioception 1, 2, and 3 videos), self-stretching (self-stretching video), and postural correction in the sitting position (at the end of the joint gliding mobilization video and the stabilization and proprioception 2 video)

The patient should perform all exercises, correctly learned in the treatment, at home once daily (25-30 minutes), avoiding the painful exercises. Be careful with the environment (eg, light on bedside table; lifting heavy objects, especially away from the body).



Postural correction (elbow joint behind the shoulder girdle) (joint gliding mobilization video)



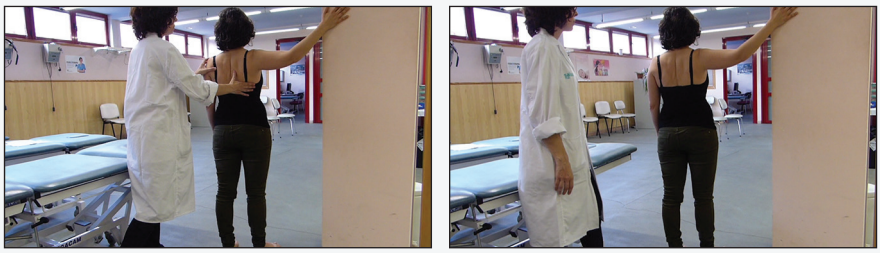
Infraspinatus muscle self-stretching (self-stretching video)

Upper trapezius muscle self-stretching (self-stretching video)

Levator scapulae muscle self-stretching (self-stretching video)

APPENDIX A

Pectoralis minor muscle self-stretching (self-stretching video)



Pectoralis major muscle self-stretching (self-stretching video)

The material used included a bench, chair, mirror, and Kaltenborn wedge, which was obtained during the Kaltenborn training. All treatments were applied in the physical therapy consultation in the health center of primary care. The patients were treated in their health center; they lived in and belonged to that health area.

A written document titled *Procedural Manual* was the guide of the intervention, both for exploration and treatment, and the applied techniques, the number of sessions, and content thereof were gathered in it.

Schedule

Ten sessions were individually applied: 2 sessions per week for 5 weeks. The length of each session was approximately 30 minutes. The number of sessions were increased (1-2) in some patients to guarantee correct learning of exercises, without any additional treatment. The therapy gradually increased in difficulty and in number of techniques, always following the order of MT1, MT2, MT3, MT4, and MT5, as previously described.

Personalized Treatment

First Session

MT1 and MT2:

- Passive glenohumeral gliding in the supine position (to explain to the patient what we are doing) and passive scapulothoracic joint gliding

MT3:

- Passive stretching during breathing out in necessary muscles, in supine (levator scapulae, upper trapezius, pectoralis minor) and in sidelying (lower trapezius, serratus anterior, rhomboid)

MT4:

- First postural re-education, with scapular relocation in supine, to introduce lumbar correction and breathing out
- Scapular dissociation exercises in the sitting position in front of a mirror

MT5:

- Recommend that the patient pay attention to the position of the shoulder in activities of daily living (have postural awareness)

Second Session

Same as the first session

Third Session

MT1 and MT2:

- Passive glenohumeral gliding in supine (in different grades of abduction) and in the sitting position, and passive scapulothoracic joint gliding

MT3:

- Passive stretching during breathing out in necessary muscles, in the supine, sidelying, and sitting positions (levator scapulae, upper trapezius, pectoralis minor, pectoralis major, supraspinatus, biceps brachii, lower trapezius, serratus anterior, rhomboid, infraspinatus, teres minor, posterior deltoid)

APPENDIX A

MT4:
- Humeral stabilization in supine (drawing in air)
- Continue with scapular relocation in supine, with breathing out
- Continue scapular dissociation exercises and introduce correction of the lumbar spine in the sitting position (global position in relation to lumbar and scapular posture)

MT5:
- Teach self-scapular relocation in supine and self-stretching of stretched muscles at the treatment session

Fourth Session

MT1 and MT2:
- Passive glenohumeral gliding in the sitting position and passive scapulothoracic joint gliding

MT3:
- Same stretching muscles

MT4:
- Humeral stabilization in supine and in the standing position (in correct position, isometric contractions against the wall)
- Continue with scapular dissociation
- Introduce scapular static stabilization in front of the wall (90° of flexion if possible, pushing and pulling) and dynamic scapular stabilization exercises in standing (only retraction/protraction)

MT5:
- Teach the stretching of the supraspinatus and infraspinatus in sitting and the pectoralis minor with the wall. If the patient is not able to correctly reproduce it, do not have the patient perform at home yet. Supervise the learned self-stretching

Fifth Session

Same as the fourth session

Sixth Session

MT1 and MT2:
- Passive glenohumeral gliding in the sitting position
- Active glenohumeral gliding in the sitting position, with exteroceptive stimulus (mainly posterior)

MT3:
- Continue with all necessary stretching

MT4:
- Continue with humeral stabilization, scapular dissociation, and static and dynamic scapular stabilization exercises, and introduce drawing with the hand over the wall in the standing position

MT5:
- Continue teaching and supervising the exercises. Supervise exercises to perform at home

Seventh Session

MT1 and MT2:
- Active glenohumeral gliding in sitting in front of a mirror

MT4:
- Improve humeral stabilization, in the right position, and the scapular dissociation and stabilization exercises, in front of a wall

MT5:
- Supervise all self-stretching and all previous exercises. The patient should already know all recommendations and exercises. Consult with patient regarding any doubts about treatment

Eighth Session

Same as the seventh session

Ninth Session

MT5:
- In this session, the patient should know the active gliding, scapular correction, active self-stretching, humeral stabilization, and static and dynamic scapular stabilization exercises, performed in front of the wall. Supervise and correct the exercises. Answer questions

Tenth Session

MT5:
- Supervise, emphasizing the most important aspects for each patient. Assess any specific intervention adherence or fidelity

APPENDIX B

OUTCOME DATA FOR NOCTURNAL PAIN

Nocturnal Pain	Baseline	Posttreatment	After 3 mo
Personalized treatment			
No	22	32	35
Yes	41	31	28
Personalized treatment plus dry needling			
No	16	37	34
Yes	41	20	23
Within-group change from baseline			
Personalized treatment			
No at baseline			
No		16*	15†
Yes		6*	7†
Yes at baseline			
No		16*	20†
Yes		25*	21†
Personalized treatment plus dry needling			
No at baseline			
No		12‡	13‡
Yes		4‡	3‡
Yes at baseline			
No		25‡	21‡
Yes		16‡	20‡
Between-group comparison of improvement			
Personalized treatment improved		16§	20
Personalized treatment plus dry needling improved		25§	21
Odds ratio‖		0.41 (0.17, 0.99)	0.91 (0.38, 2.15)

**P value calculated with the McNemar test (P>.05).*
†P value calculated with the McNemar test (P<.01).
‡P value calculated with the McNemar test (P<.001).
§P<.05 with the chi-square test.
‖Values in parentheses are 95% confidence interval.