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Bibliographic Data	
Authors	Arias-Buria JL, Fernandez-de-las-Penas C, Palacios-Cena M, and et al.
Title	Exercises and Dry Needling for Subacromial Pain Syndrome: A Randomized Parallel-Group Trial
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Citation	The Journal of Pain, Vol 18, No. 1 (January), 2017: pp 11-18.
Other information if relevant	Trial Registration with clinicaltrials.gov, number NCT02338908

Methods	
Aim of study	To compare the effectiveness on pain and disability of exercise versus exercise plus trigger point (TrP) dry needling (TrP-DN) in subacromial pain syndrome.
Design	Double-blind parallel group randomized clinical trial

Participants	
Population from which participants are drawn	Consecutive subjects with a diagnosis of subacromial pain syndrome were recruited from a local regional hospital in Madrid, Spain during routine medical visits.
Setting (location and type of facility)	Physical therapy clinic
Age	adults 18 to 65 years of age, mean age 48.5 years
Sex	37 men, 13 women, total 50 at baseline
Total number of participants for whom outcome data were reported	At the primary endpoint of 12 months, 47 (94%) reported outcome data and completed follow-up. Outcome data were reported on 50 participants at 1 week post-treatment and at 3 months, 49 at 6 months, and 47 at 12 months.
Inclusion criteria	1) unilateral nontraumatic shoulder pain, 2) shoulder pain for at least 3 months, 3) pain intensity of at least 4 points on an 11-point numeric pain rating scale (NPRS), 4) diagnosis of subacromial pain syndrome
Exclusion criteria	1) bilateral shoulder symptoms, 2) younger than 18 or older than 65 years, 3) history of shoulder fractures or dislocation, 4) diagnosis of cervical radiculopathy, 5) previous interventions with steroid injections in the shoulder area, 6) fibromyalgia syndrome, 7) previous history of shoulder or neck surgery, 8) any type of intervention for the neck-shoulder area during the previous year, 9) fear of needles, or 10) blood coagulation disorders.
Other information if relevant	There were no significant differences between groups in participants' baseline sociodemographic, clinical characteristics, or outcome measure scores. Participants had subacromial pain an average of 6 years.

Intervention Groups

Group 1	
Group name	Trigger point dry needling (TrP-DN) plus exercise group
Number in group	25 at baseline
Description of intervention	The **exercise program** consisted of eccentric loading exercises for the shoulder musculature which included 3 exercises focusing on supraspinatus, infraspinatus, and scapular stabilizer musculature and each exercise was performed in 3 sets of 12 repetitions. The exercise program was taught by an experienced physical therapist in the first session and monitored in 4 subsequent sessions, once per week during the 5-week treatment period. Each session lasted approximately 20 to 25 minutes. Participants were asked to perform the exercise program on an individual basis twice every day for 5 weeks. Participants also received **TrP-DN** to active TrPs in shoulder muscles that referred pain or reproduced shoulder symptoms during the second and fourth treatment sessions. The muscles included for possible TrP-DN included the anterior and middle deltoid, supraspinatus, infraspinatus, teres minor and major, and subscapularis. Participants received TrP-DN with disposable stainless steel needles of .32mm X 40mm that were inserted into the skin over the TrP penetrating the skin into the TrP area until the first local twitch response was obtained. The needle was moved up and down until the twitch stopped. The depth of the needle depended on the muscle and ranged from10 to 15mm for the infraspinatus or deltoid muscles to 30 to 35 mm for the supraspinatus and teres major and minor muscles. TrP-DN lasted 5 to 10 minutes and was applied by a physical therapist with 10 years of clinical experience.
Duration of treatment period	5 weeks of exercise, 2 exercise sessions per day lasting approximately 20 to 25 minutes each. Two treatments of TrP-DN, once in week 2 and once in week 4.
Co-interventions if reported	none
Additional information if relevant	Participants were monitored during the entire 5 week treatment period for proper adherence to the exercise protocol for obtaining a 90 to 95% rate of daily practice.

Group 2	
Group name	Exercise alone group
Number in group	25 at baseline
Description of intervention	Both groups received the same exercise program. (See description above).
Duration of treatment period	5 weeks of exercise, 2 exercise sessions per day lasting approximately 20 to 25 minutes each.
Co-interventions if reported	none
Additional information if relevant	Participants were monitored during the entire 5 week treatment period for proper adherence to the exercise protocol for obtaining a 90 to 95% rate of daily practice.

Primary outcome	
Outcome name and criteria for definition	The primary outcome measure was 1-year improvement in shoulder pain-related disability. Related disability was assessed with the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire. It consists of 30 items on a 100 point scale where higher scores reflect greater disability. The minimal clinically important difference (MCID) for the DASH is 10.8 points.
Time points measured and/or reported	At baseline, 1 week after the last treatment, and 3, 6, and 12 months after the end of therapy by a blinded assessor.
Differences between groups	Both groups demonstrated statistically significant and clinically meaningful improvements in function at all follow-up periods. At the 12 months follow-up, the TrP-DN group reduced their DASH score from baseline by 59.7 points, and the exercise only group reduced the DASH by 46.5 points. By one week after the end of treatment, both groups exceeded the MCID of 10.8 points. For between-group differences over time, the TrP-DN group exhibited statistically significant ($P < .001$) and clinically greater improvements in function at all follow-up periods than those receiving exercise alone. Between group differences in the DASH 1 week after the last treatment were 20.6 points[95% CI 23.8 to 17.4]; at 3 months: 23.2 points [95%CI 28.3 to 18.1]; at 6 months: 23.6 points [95% CI 28.9 to 18.3]; and at 12 months: 13.9 [95% CI 17.5 to10.3]. Between-group effect sizes were large (1.1 to 1.6) at all follow-up periods in favor of the TrP-DN group.
Additional information if relevant	No serious clinical adverse effects were reported. Five patients in the TrP-DN group experienced muscle soreness after the first dry needling session. Two participants in the exercise group and one in the TrP-DN group were lost to follow-up.

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were: 1) Current level of shoulder pain 2) Worst level of pain experienced in the preceding week 3) Number of successful outcomes in patients attaining 50% improvement in DASH score from baseline at 6- and 12-month follow-ups. An 11-point Numerical Pain Rating Scale (NPRS) (0 = no pain, 10 = maximum pain) was used to assess the patients' pain intensity. The MCID is 1.1 points.
Time points measured	At baseline, 1 week after the last treatment, and 3, 6, and 12 months after the end of therapy by a blinded assessor.
Differences between groups	- Both groups had similar reductions in current and worst shoulder pain at all follow-up periods. Both groups exhibited clinically meaningful moderate to large within-group effect sizes (.7 to 1.4) at 3-, 6-, and 12-month follow-ups. - There were no statistically significant differences between groups for mean current shoulder pain ($P=.582$) or mean worst shoulder pain ($P=.668$) from baseline at all follow-up points. - A greater number of patients in the TrP-DN group experienced a successful outcome in the intention to treat analyses at 6 ($P < .001$) and 12 month ($P = .047$) follow-up periods. All 24 patients in the TrP-DN group experienced a successful outcome at 6 and 12 months, while only 15 and 19 patients experienced a successful outcome at 6 and 12 months, respectively.

Additional information if relevant	ITT analysis results were reported.
Conclusions	
Key Conclusions Of Study Authors	- This RCT found that inclusion of TrP-DN into an exercise program resulted in greater improvements on shoulder-related disability in subjects with subacromial pain syndrome at 3-, 6-, and 12-month follow-ups. - Participants receiving TrP-DN in addition to exercises exhibited clinically better outcomes in pain-related disability at all follow-up periods than those individuals who received the exercise program alone. Between-group change scores and their 95% CIs surpassed the MCID of 10.8 points for shoulder pain-related disability in favor of the TrP-DN group at all follow-up periods, supporting a clinically meaningful effect of this intervention. - No significant differences in shoulder pain were observed, since both groups experienced similar reductions in pain from baseline at all follow-up periods. - This study found that both groups experienced a similar decrease in mean current and worst shoulder pain supporting the effectiveness of exercises for the management of subacromial pain syndrome. Within-group change scores and their 95% CIs surpassed the MCID of 1.1 points for shoulder pain at 3, 6, and 12 months in both groups, supporting a clinical effect of the exercise program at both a medium- and long-term follow-up. - All participants allocated to the TrP-DN group attained a successful treatment outcome for pain-related disability (reduction of at least 50%) at 6 and 12 month follow-ups. - The current trial suggests that TrPDN can be clinically used for improving effects of exercise programs in people with subacromial pain syndrome.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomization was done using a computer-generated randomized table of numbers created by a statistician who did not participate in the main trial.
Allocation concealment *(selection bias)*	Low	Individual and sequentially numbered index cards with the random assignment were prepared, folded, and placed in sealed opaque envelopes. A second external researcher opened the envelope and proceeded with allocation.
Blinding of participants and personnel *(performance bias)*	Low	Subjects and investigators were blinded to group allocation.
Blinding of outcome assessment *(detection bias)*	Low	Examiners blinded to group allocation obtained all outcome measures.
Incomplete outcome data *(attrition bias)*	Low	Loss to follow up was low and relatively equal between groups. All participants lost to follow-up were included in the ITT analysis.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with clinicaltrials.gov, number NCT02338908.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Not reported	
Possible conflicts of interest for study authors	The authors have no conflicts of interest to declare.	
Notes:		

Comments by DOWC staff

- This study found that the inclusion of 2 sessions of trigger point dry needling (TrP-DN) into a twice daily 5-week exercise program was significantly more effective in improving shoulder pain-related disability than an exercise program alone at 3, 6, and 12 month follow-ups in people with subacromial pain syndrome.

- The findings of this study showed that there were similar, significant and clinically meaningful improvements in the average current and worst pain intensity during the preceding week over the 12 month study period for both groups, but these reductions in pain were not statistically different between the groups. The addition of trigger point dry needling (TrP-DN) into a twice daily 5-week exercise program was not more effective in reducing pain than an exercise program alone at 3, 6, and 12 month follow-ups in people with subacromial pain syndrome.

- The authors reported that adherence with the home exercises was good for both intervention groups with a 90 to 95% rate of daily practice.

- Most participants reported that they did not continue with the exercise program after the 5-week treatment period, only sporadically when they had an exacerbation of pain.

- It is not known if a greater number of trigger point dry needling sessions would have resulted in larger differences between interventions. There exists no current scientific data on the adequate frequency and dose of therapy.

- Because dry needling is applied to active trigger points, it is possible that subgroups of individuals with subacromial pain syndrome without active trigger points would not benefit from this intervention.

- Study strengths included an adequate sample size with adequate statistical power to detect clinically meaningful effects, trial registration, a pre-specified protocol, design features known to minimize bias such as subject, investigator, and assessor blinding, concealed allocation, an intention-to-treat analysis, and a long-term follow-up with high rates of follow-up.

- The main limitations of the study were that participants were recruited from a single clinic which may decrease the generalization of the results, and not including a no-intervention control group or a sham needling group to prevent a placebo effect.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that the inclusion of 2 sessions of trigger point dry needling into a twice daily 5-week exercise program was significantly more effective in improving shoulder pain-related disability than an exercise program alone at 3, 6, and 12 month follow-ups in people with subacromial pain syndrome. Both interventions were equally effective in reducing pain over 12 months.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant