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Title Page

Exercises and Dry Needling for Subacromial Pain Syndrome: a Randomized Parallel-Group Trial

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Abstract

This randomized clinical trial investigated the effectiveness of exercise vs. exercise plus trigger point dry needling (TrP-DN) in subacromial pain syndrome. A randomized parallel-group trial, with 1-year follow-up was conducted. Fifty subjects with subacromial pain syndrome were randomly allocated to receive exercise alone or exercise +TrP-DN. Participants in both groups were asked to perform an exercise program of the rotator cuff muscles twice daily for 5 weeks. Further, patients allocated to the exercise +TrP-DN group also received dry needling to active TrPs in the muscles reproducing shoulder symptoms during the 2nd and 4th sessions. The primary outcome was pain-related disability assessed with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Secondary outcomes included mean current pain and the worst pain experienced in the shoulder during the previous week. They were assessed at baseline, one week, and 3, 6, and 12 months after the end of treatment. Analysis was by intention to treat with mixed ANCOVA adjusted for baseline outcomes. At 12 months, 47 (94%) patients completed follow-up. Statistically larger improvements (all, $P<0.01$) in shoulder disability was found for the exercise +TrP-DN group at all follow up periods [post: Δ -20.6 (-23.8 to -17.4); 3 months: Δ -23.2 (-28.3 to -18.1); 6 months: Δ -23.6 (-28.9 to -18.3); 12 months: Δ -13.9 (-17.5 to -10.3). Both groups exhibited similar improvements in shoulder pain outcomes at all follow-up periods. The inclusion of TrP-DN to an exercise program was effective for improving disability in subacromial pain syndrome. No greater improvements in shoulder pain were observed.

Trial registration: http://www.clinicaltrials.gov, ClinicalTrials.gov, NCT02338908.

Keywords: subacromial pain syndrome, exercise, trigger point, dry needling.

Perspective

This study found that the inclusion of two sessions of trigger point dry needling into an exercise program was effective for improving shoulder pain-related disability at short-, medium- and long-term; however, no greater improvement in shoulder pain was observed.

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Exercises and Dry Needling for Subacromial Pain Syndrome: a Randomized Parallel-Group Trial

Introduction

Shoulder pain is a significant health problem presenting a prevalence of 25% in the general population.[25] Tekavec et al found that the most prevalent diagnosis is subacromial pain syndrome.[32] The societal burden of shoulder pain is substantial with annual costs per patient estimated at €4139 in primary health care[33] and direct costs for the treatment of shoulder disorders in the United States over $7 billion.[28]

Conservative treatment is the first therapeutic option for individuals with shoulder pain;[13] however the most appropriate treatment strategy is unclear. Therapeutic exercise probably exhibits the highest level of evidence for the treatment of shoulder pain conditions including subacromial pain syndrome,[27,30] although further trials are required.[12] In fact, the Dutch Orthopedic Association Clinical Practice Guideline for subacromial pain syndrome recommends exercise as the first therapeutic option, but also that inactivation of trigger points (TrPs) shoulder be considered.[8] TrPs are defined as hypersensitive tender spots within taut bands of skeletal muscles that are painful, elicit a referred pain, and generate motor dysfunctions.[31] Previous studies have demonstrated that active TrPs in the shoulder muscles reproduce symptoms suffered by subjects with subacromial pain syndrome.[4,16]

Several therapeutic approaches, pharmacological and non-pharmacological, are proposed for the management of active TrPs, with manual therapies, trigger point injections, and dry needling (TrP-DN) being among the most commonly used. [7] Some evidence suggests that

manual therapy targeting active TrPs in the shoulder musculature is effective for reducing pain and improving function in individuals with shoulder pain in the short-term,[3] but there is no evidence on mid- and long-term effects. Dry needling (TrP-DN) is defined as a "skilled intervention using a thin filiform needle to penetrate the skin that stimulates TrPs, muscles, and connective tissue for the management of musculoskeletal disorders".[2] Recent meta-analyses suggest that TrP-DN may be effective for neck and shoulder pain immediately after and at medium terms.[21,23] However, no study has investigated long-term effects of TrP-DN in patients with shoulder pain. Our objective was to conduct a randomized clinical trial to compare the 1-year effectiveness on pain and disability of the inclusion of TrP-DN into an exercise program for people with subacromial pain syndrome.

Methods

Study Design

This randomized, parallel-group clinical trial compared 2 treatments for subacromial pain syndrome: exercise only and TrP-DN plus exercise. The primary end point was 1-year improvement shoulder pain-related disability. Secondary outcomes included the current mean of shoulder pain and the worst level of pain experienced in the preceding week in the shoulder. The current report follows the CONSORT (Consolidated Standards of Reporting Trials) extension for clinical trials.[35] The study was approved by the Institutional Review Board of Universidad Rey Juan Carlos (URJC 31/2014) and the clinical trial was registered (ClinicalTrials.gov: NCT02338908).

Participants

Consecutive subjects with a diagnosis of subacromial pain syndrome from a local regional Hospital (Madrid, Spain) were screened for eligibility criteria. Participants were invited to participate into the study during routine medical visit. To be eligible, they had to fulfill the following criteria: 1, unilateral non-traumatic shoulder pain; 2, shoulder pain from at least 3 months; and, 3, pain intensity of at least 4 points on an 11-point numerical pain rate scale (NPRS). In our study, subacromial pain syndrome was diagnosed following the Dutch Orthopedic Association Clinical Practice Guideline where a cluster of tests has been proposed. Therefore, patients were diagnosed when they exhibited a positive painful arc test during shoulder abduction (+LR 3.7, 95%CI 1.9-7.0),[14] and at least 2 positive of the following clinical tests: Hawkins-Kennedy test (+LR 1.70, 95%CI 1.29-2.26), Neer's sign (+LR 1.86, 1.49-2.31), empty can test (specificity 0.62), drop arm test (specificity 0.92), or lift-off test (specificity 0.97).[1] Patients were excluded if they exhibited: 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; or, 8, any type of intervention for the neck-shoulder area during the previous year. Additionally, since fear of needles is present in around 20-25% of subjects attending general medical practice[34], we also excluded patients with fear of needles and coagulation disorders for avoiding any potential risk on the experimental group. All participants signed an informed consent prior to their inclusion in the study.

Randomization and masking

Patients were randomly assigned to receive TrP-DN plus exercise or exercise alone. Concealed allocation was done using a computer-generated randomized table of numbers created by a statistician who do not participate in the main trial. 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. Examiners blinded to group allocation obtained all outcome measures.

Interventions

Both groups received the same exercise program. No consensus exists on what exercises should be applied on individuals experiencing subacromial pain syndrome; however, it is recommended that they should be specific and of low intensity and high frequency.[5,8] Therefore, each exercise was performed in 3 sets of 12 repetitions. Each repetition included the concentric phase and after the eccentric phase of the exercise, which was slowly conducted. The program consisted of 3 exercises focusing on supraspinatus, infraspinatus, and scapular stabilizer musculature. The exercise program was taught by an experienced physical therapist in the 1st session and monitored in subsequent 4 sessions, once per week during the treatment period. Each session lasted approximately 20-25min. Participants were asked to perform the exercise program on an individual basis twice every day for 5 weeks. They were monitored during all the treatment period for proper adherence to the exercise protocol for obtaining a 90%-95% rate of daily practice. During the follow-up period, participants were asked for doing exercise at demand, which was monitored on subsequent follow-up assessments.

Patients allocated to the TrP-DN group also received TrP-DN to active TrPs in those shoulder muscles which referred pain or reproduced shoulder symptoms during the second and fourth treatment sessions. Therefore, patients allocated to this group received the same instructions for the exercise program in the first session, and TrP-DN during the 2nd and 4th sessions where participants also performed the exercise program monitored by the clinician. The muscles included in physical examination included the anterior and middle deltoid, supraspinatus, infraspinatus, teres minor and major, and subscapularis.[4,16] Since some muscles can exhibit multiple TrPs[10] a clinically pragmatic approach was applied. Therefore, if multiple active TrPs were found, the clinician selected the most painful for receiving TrP-DN. Participants received TrP-DN with disposable stainless steel needles of 0.32mm*40mm (Novasan©, Madrid, Spain) that were inserted into the skin over the TrP. In this study, the fast-in and fast-out technique described by Hong[17] was applied. Once the active TrP was located, the overlying skin was cleaned with alcohol. The needle was inserted penetrating the skin into the TrP area until the first local twitch response was obtained. The depth of the needle depended on the muscle and ranged from 10-15 mm for the infraspinatus (**Fig. 1**) or deltoid (**Fig. 2**) muscles to 30-35 mm for the supraspinatus and teres major and minor muscles. Hong[17] suggested that local twitch responses should be elicited during TrP-DN for a proper and successful technique. Once the first local twitch response was obtained, the needling was hence moved up and down (3 to 5 mm. vertical motions with no rotations) at approximately 1Hz until no more local twitch responses were elicited. TrP-DN intervention had a mean duration of 5-10 min in all participants. TrP-DN was applied by a physical therapist with 10 years of clinical experience in this therapeutic approach.

Outcome Measures

Clinical records of all subjects included questions regarding the location, intensity, and duration of the symptoms, aggravating and relieving factors, and previous treatments. Pain and related-disability outcomes were assessed at baseline (pre), one week after the last treatment (post), and 3, 6, and 12 months after the end of therapy. It has been found that the intensity of shoulder pain and related-disability are highly associated in patients with subacromial shoulder pain;[22] however, shoulder related-disability is the strongest predictor for physical therapy interventions.[6] Therefore, we decided shoulder related-disability as the primary outcome. Related-disability was assessed with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire.[18] It consists of 30-items assessing: 1, degree of difficulty during the preceding week in performing physical activities because of problems in the upper extremity (21 items); 2, severity of each pain symptom, activity-related pain, tingling, weakness, and stiffness (5 items); and, 3, the problem's effect on social activities, work, and sleep, and its psychological impact (4 items). Each item is answered on a 5points scale ranging from 1 (no difficulty to perform, no symptom, or no impact) to 5 (unable to do, very severe symptom, or high impact). Responses are summed to form a raw score that is converted to a 0 to 100 scale where higher scores reflect greater related-disability.[18] The Spanish version of the DASH has shown high internal consistency (Cronbach α: 0.96) and excellent test-retest reliability (r: 0.96).[15] It has been recently reported that the MCID for the DASH is 10.8 points.[9]

The secondary outcome was the intensity of shoulder pain. An 11-points NPRS (0: no pain; 10: maximum pain) was used to assess the patients' current level of shoulder pain and the worst level of pain experienced in the preceding week.[20] Mintken et al[29] found that the MCID for the NPRS in individuals with shoulder pain was 1.1 points.

We also defined a successful outcome when patients observed a 50% improvement from baseline in DASH at 6 and 12 months follow-up periods.

Treatment Side Effects

Patients were asked to report any adverse event that they experienced either after the intervention or during any other part of the study. In the current study, an adverse event was defined as sequelae with any symptom perceived as distressing and unacceptable to the patient and required further treatment.

Sample size determination

The sample size calculations were based on detecting between-groups differences of 10.8 points (MCID) on the main outcome measure,[9] assuming a standard deviation of 10.5, a 2-tailed test, an alpha level (α) of 0.05 and a desired power (β) of 90%. The estimated desired sample size was calculated to be at least 21 subjects per group. A dropout rate of 15% was expected, so 25 patients were included in each group.

Statistical Analysis

Statistical analysis was performed using SPSS software, version 21.0 (Chicago, IL, USA) and it was conducted according to intention-to-treat analysis for patients in the group to which they were allocated. Baseline demographic and clinical variables were compared between both groups using independent Student t-tests for continuous data and $\chi 2$ tests of independence for categorical data. Our primary evaluation included mixed-model repeated

measured analyses of covariance (ANCOVA) with time as the within-subjects factor, group as the between-subjects factor, and adjusted for baseline outcomes for evaluating between-group differences in all the outcomes. Gender was also included in the main analysis as covariate. We used $\chi 2$ tests to compare success rate at 6 and 12 months between groups. To enable comparison of effect sizes, standardized mean score differences (SMDs) were calculated by dividing the mean score differences between groups by the pooled standard deviation.

Results

Between January and March 2015, 60 consecutive individuals with shoulder pain were screened for eligibility criteria. Fifty (83%) satisfied all criteria, agreed to participate, and were randomly allocated into exercise (n=25) or TrP-DN plus exercise (n=25) group. Randomization resulted in similar baseline features for all variables (**TABLE 1**).

Within patients allocated to the exercise group, 2 were lost at 12 months of follow-up because they received corticosteroid injection in the shoulder, whereas 1 patient allocated to the exercise + TrP-DN group was lost at 6-months follow-up due to a whiplash injury. The reasons for ineligibility can be found in **Fig. 3**, which provides a flow diagram of patient recruitment and retention. None of the participants in either group reported any other therapeutic intervention during the study, excluding the use of NSAID at demand but sporadically. In fact, most participants reported that they did not continue with the exercise program during the follow-up period, only sporadically when they have an exacerbation of pain. Five patients assigned to the exercise plus TrP-DN (25%) experienced muscle

soreness after the first DN session which resolved spontaneously within 24-36 hours. No clinical adverse events were reported by the participants.

Adjusting for baseline outcomes, the mixed-model ANCOVA observed significant Group*Time interaction for DASH (F=13.449; P<0.001). Patients receiving exercise plus TrP-DN exhibited higher improvements in function at all follow-up periods [immediately after: Δ -20.6 (-23.8 to -17.4); 3 months: Δ -23.2 (-28.3 to -18.1); 6 months: Δ -23.6 (-28.9 to -18.3); and 12 months: Δ -13.9 (-17.5 to -10.3), all P<0.001] than those receiving the exercise protocol alone (**Fig. 4**). Between-group effect sizes were large at all follow-up periods (1.1>SMD>1.6) in favor of the exercise plus TrP-DN group. The inclusion of gender as covariate did not influence the results on shoulder disability (F=0.861; P=0.358).

The ANCOVA did not reveal significant Group*Time interactions for mean current (F=0.307; P=0.582) and the worst intensity (F=0.187; P=0.668) of shoulder pain: both groups get similar changes in shoulder pain at all follow-up periods (**TABLE 2**). No significant between-groups differences were observed at any follow-up period (P>0.43). Both groups exhibited moderate to large within-group effect sizes (0.7> SMD>1.4) at 3, 6 and 12 months follow-ups (**Fig. 4**). Again, these results were not significantly different by gender (mean pain: F=0.409, P=0.536; the worst experienced pain: F=0.020, P=0.888)

A greater number of patients allocated to the exercise + TrP-DN group experienced a successful outcome in the intention-to-treat analyses at 6 (P<0.001) and 12 (P=0.0.47) month follow-up periods (**TABLE 3**).

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Discussion

This is the first study investigating the effect of adding TrP-DN to a standard exercise intervention for the treatment of subacromial pain syndrome. This randomized clinical trial found that inclusion of TrP-DN into an exercise program resulted in higher improvements on shoulder related-disability in subjects with subacromial pain syndrome at 3, 6 and 12 month follow-ups. No significant differences in shoulder pain were observed, rather, both groups experienced similar improvements from baseline to all follow-up periods.

The Dutch Orthopedic Association Clinical Practice Guideline proposes the use of exercises for the management of individuals with subacromial pain syndrome.[8] Further, recent systematic reviews also support the effectiveness of exercise in subacromial shoulder pain.[27,30] Our study found that both groups experienced similar decrease in mean current and the worst shoulder pain supporting the effectiveness of exercises for the management of subacromial pain syndrome. Within-group change scores and their 95% confidence intervals surpassed the MCID of 1.1 points for shoulder pain[29] at 3, 6 and 12 months in both groups, supporting a clinical effect of the exercise program at a medium and long-term follow-up. It is interesting to note that no changes in shoulder pain outcomes were observed in either group at 1 week post-intervention. It is possible that that dosage of exercise, the exercise loading strategy, or the exercises included in our program can explain this finding. In fact, no consensus exists on which exercise program is the best for the treatment of subacromial pain disorders.[5,8]

The novelty of this clinical trial was the application of TrP-DN for the management of subacromial pain syndrome. We observed that subjects 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 exercise program alone. In this case, between-group change scores and their 95% confidence intervals surpassed the MCID of 10.8 points for shoulder pain related-disability[9] in favor of the TrP-DN group at all follow-up periods, supporting a clinical effect of this intervention. This was supported by the fact that all patients allocated to the TrP-DN group attained a successful treatment outcome for pain-related disability (reduction of at least 50%) at 6 and 12 months.

There is evidence suggesting that TrPs are related to the presence of altered motor control patterns,[24] accelerated muscle fatigability,[11] and increased motor activation[19] in the affected and related musculature. Therefore, treatment of TrPs may effectively reduce these motor disturbances, improve motor function, and hence decrease pain-related disability. In fact, Bron et al[4] found that the number of active TrPs was moderately correlated with the DASH score in patients with shoulder pain, which could explain the current results. It is plausible that TrP-DN applied on the shoulder musculature at the beginning of an exercise program can improve the motor output of the shoulder stabilizers and facilitate proper shoulder function.

The results of this study should be considered according to potential strengths and limitations. Major strengths included that the study was prospectively registered, adhered to strict CONSORT guidelines, used blinded outcome assessment, concealed allocation, and intention-to-treat analysis. Further, the trial had high retention rates at 12 months follow-up. Among the limitations, first was that we recruited from a single clinic which may decrease the generalization of our results. Multi-centre studies controlling for site and clinician effects (cluster effects) in future trials might enhance the generalizability. Second, because we did not include a no-intervention control group, we cannot be sure that the observed

improvements are due to natural history of the condition, although this in unlikely due to chronicity of the symptoms. Third, we did not include a sham needling technique, so we cannot be sure that the benefit of TrP-DN was not simply due to placebo. Nevertheless, a recent meta-analysis concluded that real needling therapy is significantly superior to sham needling irrespective of the subtype of control or sham procedure.[26] This can be also related to the fact that we did not assess potential expectations of the participants to receive any therapeutic intervention which could potentially affect the results. Fourth, subjects allocated to the TrP-DN group received 2 sessions based on the author clinical experience since no current scientific data exists on the adequate frequency and dose of therapy. We do not know if a greater number of sessions would result in larger differences between interventions. Finally, since dry needling is applied to active TrPs, it is possible subgroups of individuals with subacromial pain syndrome without active TrPs would not benefit from this intervention. However, we contend that these factors would be unlikely to change the overall conclusion of the study.

Conclusions

In conclusion, our data indicate that the inclusion of TrP-DN into an exercise program resulted in larger clinical improvement in shoulder pain-related disability in individuals with subacromial pain syndrome. The inclusion of TrP-DN did not influence change in shoulder pain since both groups exhibited similar improvements at all follow-up periods. The current trial suggests that TrP-DN can be clinically used for improving effects of exercise programs in people with subacromial pain syndrome.

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Legend of Tables

Table 1: Baseline characteristics by treatment assignment

Table 2: Primary and secondary outcomes before and after intervention, 3, 6 and 12 months by randomized treatment assignment

Table 3: Follow-up successful outcomes (50% improvement in DASH) by randomized treatment assignment [n (%)]

Legend of Figures

Figure 1: Dry needling on active trigger points (TrPs) in the infraspinatus muscle. Copyright, David G Simons Academy™, Switzerland©, with permission

Figure 2: Dry needling on active trigger points (TrPs) in the deltoid muscle. Copyright, David G Simons Academy™, Switzerland©, with permission

Figure 3: Flow diagram of patients throughout the course of the study.

Figure 4: Evolution of all the outcomes (pain on top and DASH on bottom) throughout the course of the study stratified by randomised treatment assignment. Data are means (SE)

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Table 1: Baseline characteristics by treatment assignment

	Exercise Group (n=25)	TrP-DN + exercise Group (n=25)
Gender (male/female)	19 (76%) / 6 (24%)	18 (72%) / 7 (28%)
Age (years)	48 ± 6	49 ± 5
Years with pain	6.2 ± 1.9	5.8 ± 1.7
Side of the symptoms n (%) Right side Left side	 17 (68%) 8 (32%)	 18 (72%) 7 (28%)
Mean intensity of shoulder pain (NPRS, 0-10)	6.6 ± 1.5	7.2 ± 1.6
Worst pain experienced last week (NPRS, 0-10)	7.8 ± 0.7	8.1 ± 0.9
DASH (0-100)	62.0 ± 8.1	61.3 ± 6.5

NPRS: Numerical Pain Rate Scale; DASH: Disabilities of the Arm, Shoulder and Hand.

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Table 2: Primary and secondary outcomes before and after intervention, 3, 6 and 12 months by randomized treatment assignment

Outcome Group	Pre-intervention	Post-intervention	3 months	6 months	12 months
Mean intensity of shoulder pain (NPRS, 0-10)					
Exercise	6.6 ± 1.5 (6.0, 7.2)	6.0 ± 2.4 (5.0, 7.0)	3.4 ± 1.6 (2.4, 4.5)	2.1 ± 1.9 (1.3, 2.9)	1.6 ± 1.5 (0.8, 2.3)
TrP-DN + exercise	7.2 ± 1.6 (6.6, 7.9)	5.9 ± 2.5 (4.9, 6.9)	3.8 ± 1.5 (2.7, 4.8)	1.9 ± 2.0 (1.2, 2.8)	1.5 ± 1.4 (0.9, 2.2)
Worst level of shoulder pain experiencing preceding week (NPRS, 0-10)					
Exercise	7.8 ± 0.7 (7.4, 8.2)	5.2 ± 2.7 (4.7, 5.8)	3.3 ± 2.6 (2.6, 4.0)	2.4 ± 2.5 (1.9, 3.0)	2.0 ± 1.6 (1.5, 2.5)
TrP-DN + exercise	8.1 ± 0.9 (7.7, 8.4)	5.5 ± 2.7 (5.1, 6.1)	2.9 ± 3.0 (2.2, 3.6)	1.9 ± 3.3 (1.4, 2.5)	1.6 ± 1.9 (1.1, 2.1)
DASH (0-100)					
Exercise	62.0 ± 8.1(59.0, 65.0)	43.8 ± 6.4 (41.5, 46.1)	33.8 ± 12.0 (30.2, 37.4)	26.9 ± 12.8 (23.2, 30.7)	15.5 ± 11.1 (12.2, 18.8)
TrP-DN + exercise	61.3 ± 6.5 (58.3, 62.3)	23.2 ± 4.8 (20.9, 25.4)	10.6 ± 3.8 (7.0, 14.2)	3.4 ± 2.5 (1.5, 5.4)	1.6 ± 1.8 (0.6, 2.8)

NPRS: Numerical Pain Rate Scale; DASH: Disabilities of the Arm, Shoulder and Hand.

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Table 3: Follow-up successful outcomes (50% improvement in DASH) by randomized treatment assignment [n (%)]

	6 months follow-up		**12 months follow-up**	
	Exercise alone (n=25)	**Exercise + TrP-DN (n=24)**	**Exercise alone (n=23)**	**Exercise + TrP-DN (n=24)**
Successful outcome	15 (60%)	24 (100%)	19 (82%)	24 (100%)
Non-successful outcome	10 (40%)	0 (0%)	4 (18%)	0 (0%)

DASH: Disabilities of the Arm, Shoulder and Hand

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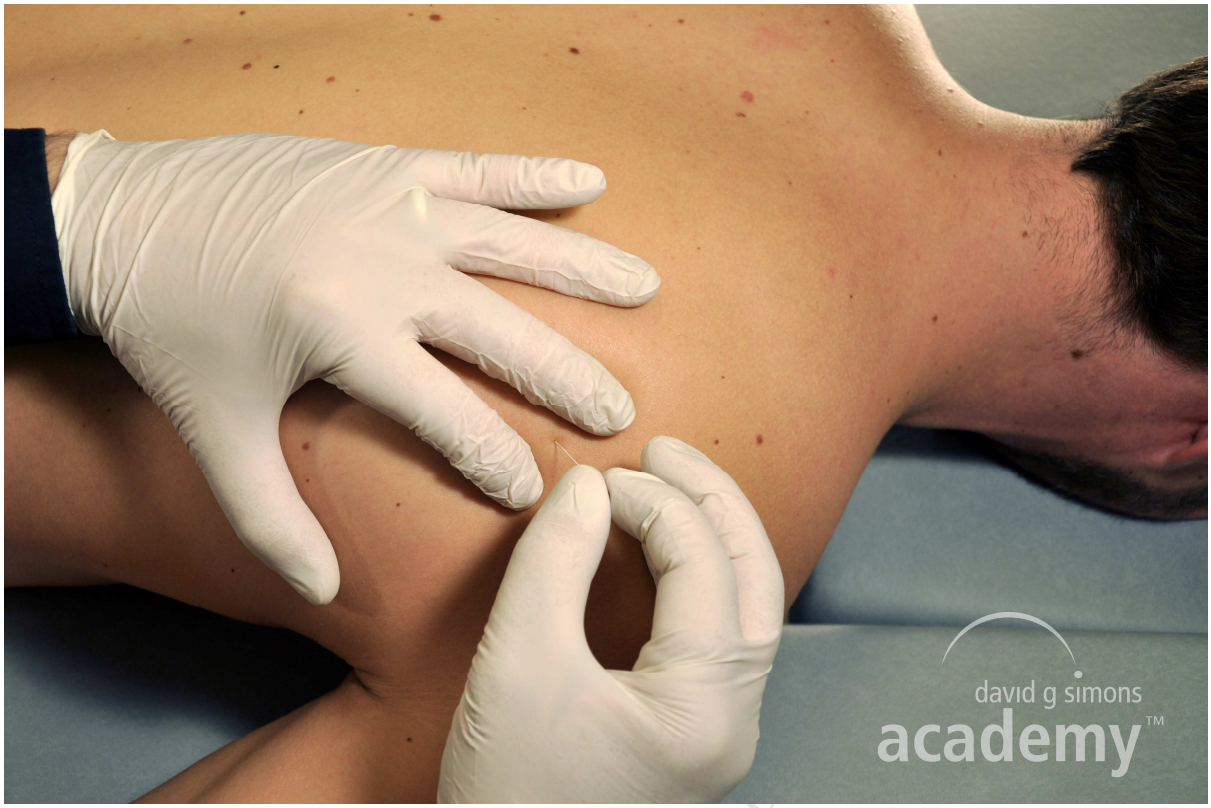

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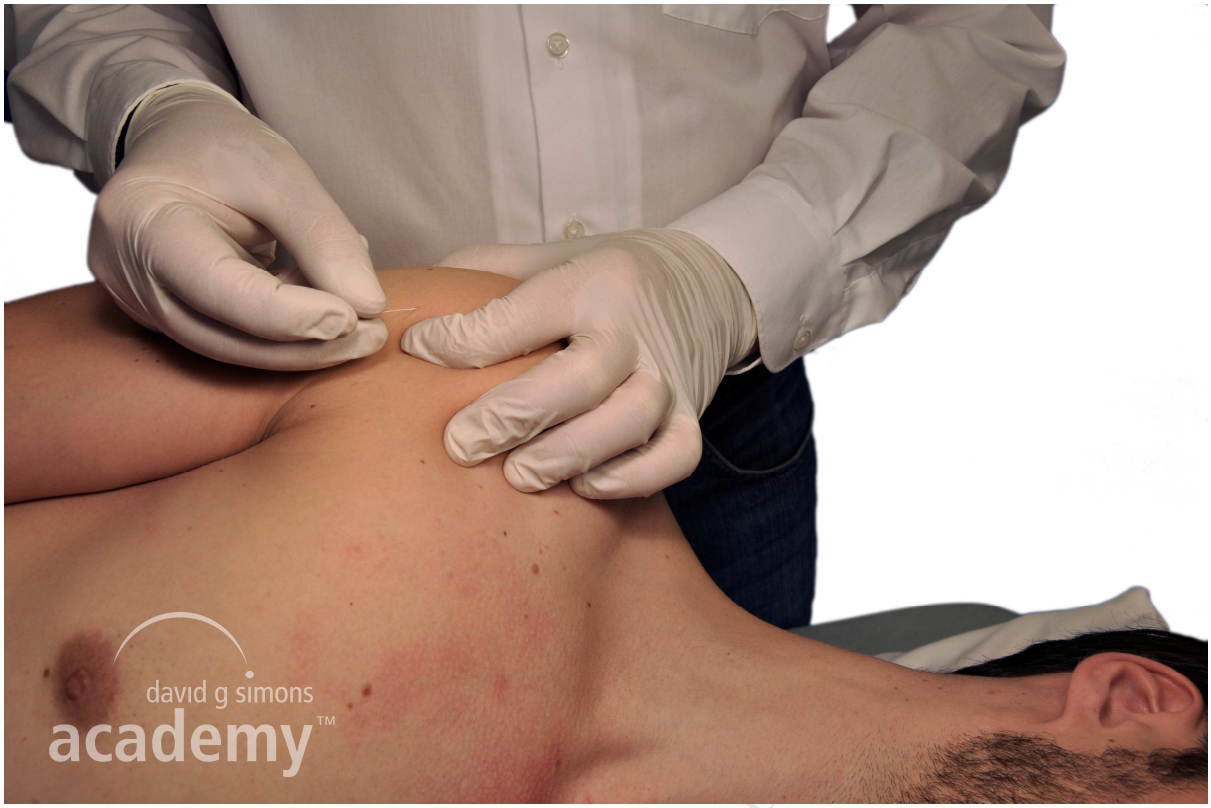

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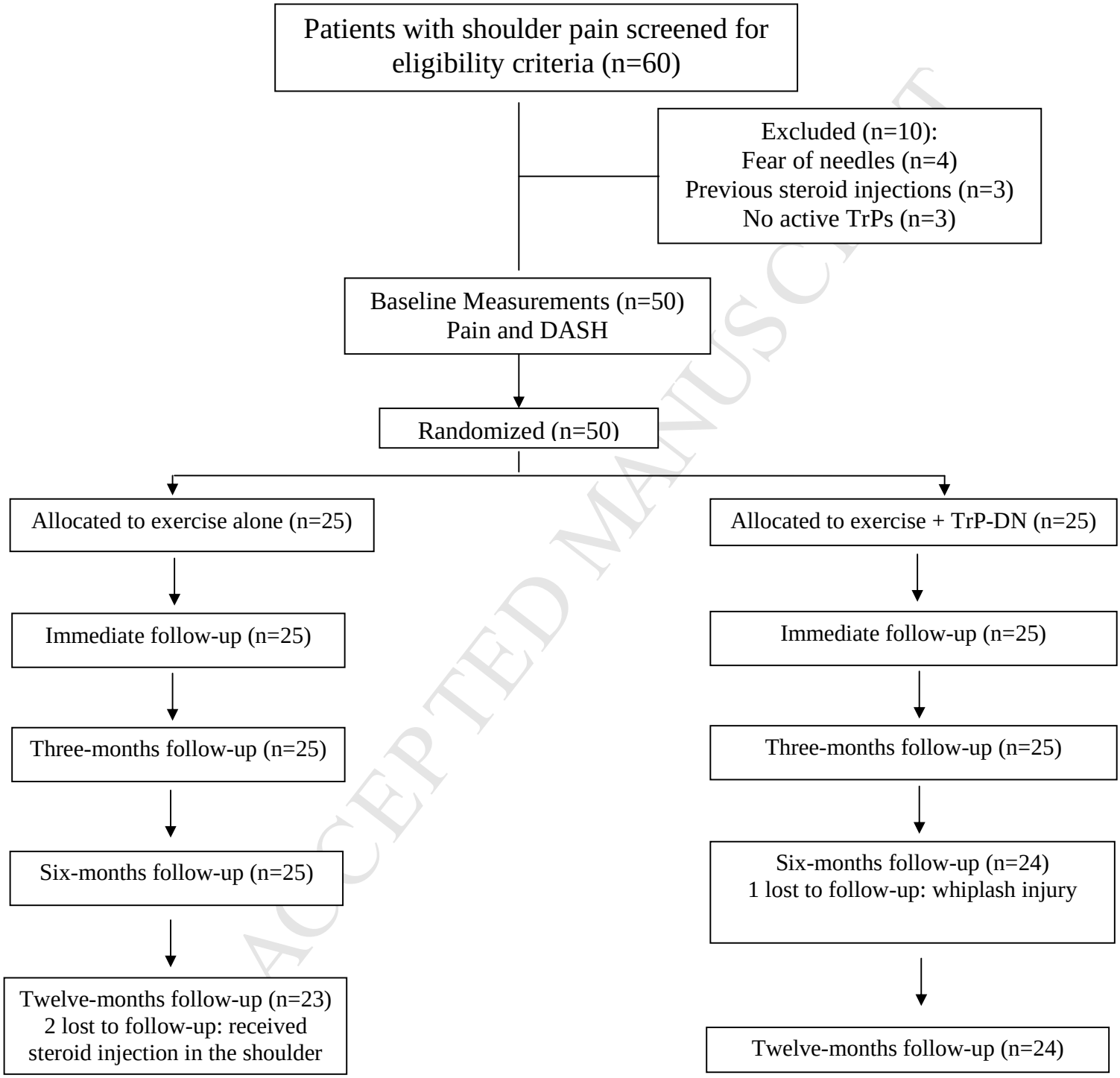
Figure 3: Flow diagram of patients throughout the course of the study



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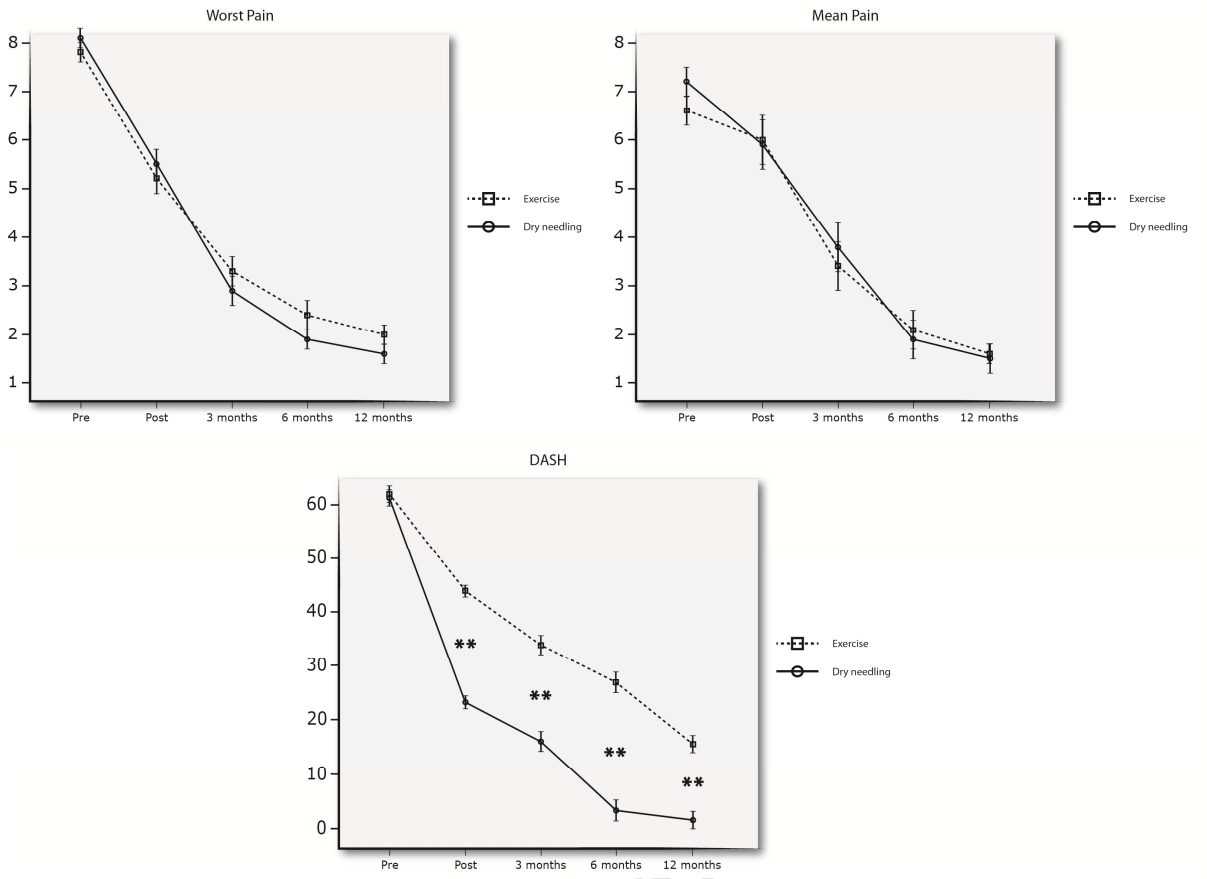

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Highlights

- We examine effectiveness the inclusion of trigger point dry needling into an exercise program for the management of subacromial pain syndrome
- The inclusion of trigger point dry needling was effective for decreasing shoulder pain-related disability at short, medium- and long-term follow-ups
- The inclusion of trigger point dry needling was not related to greater decreases in shoulder pain outcomes at short, medium- and long-term follow-ups

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