

## CRITICALLY APPRAISED TOPIC

### FOCUSED CLINICAL QUESTION

In adults (18+ years old) with myofascial trigger points, is trigger point dry needling more effective than non-invasive manual therapy techniques (massage, stretching, etc) in reducing pain severity as measured by the Visual Analogue Scale (VAS)?

### AUTHOR

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### CLINICAL SCENARIO

I treated several adult patients who were diagnosed with myofascial trigger points while on my orthopaedic clinical rotations. Many of these patients were young (20-30-year-old) otherwise healthy females who developed postural aberrations as a result of prolonged sitting at computer-based occupations. These patients commonly presented with upper quarter myofascial trigger points and related pain, specifically in their upper trapezius, posterior shoulder, and peri-spinal musculature. On one clinical rotation, my Clinical Instructor (CI) used trigger point dry needling exclusively or in combination with exercise to treat these patients. On the other clinical rotation, my CI and I used non-invasive manual therapy techniques, such as massage and ischemic compression, to treat these patients.

Based on my clinical observations and experience, there appears to be heterogeneity in treatment approaches for myofascial trigger points. While non-invasive manual therapy and therapeutic exercises have traditionally been used to address a number of impairments, including myofascial trigger points, trigger point dry needling appears to be gaining popularity among physical therapists for treatment of trigger points. It is unclear whether treatment choices are being motivated by evidence about the superiority of certain interventions, clinician preferences and anecdotal experiences, or due to other procedural issues, such as legal ability to perform dry needling based on geographical location and attainment of additional certification. Therefore, the goal of this CAT is to examine available evidence and determine whether trigger point dry needling is more effective than non-invasive physical therapy techniques in reducing pain among adult patients with myofascial trigger points. I will use this evidence in my future clinical practice to improve consistency in care among patients with myofascial trigger points. Evidence obtained through completion of this CAT will also inform my decision to obtain additional certifications to practice dry needling in the future.

### SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- One systematic review and meta-analysis and seven randomized control trials (RCTs) were reviewed for this CAT; best evidence included 2 RCTs that examined trigger point dry needling plus manual therapy and therapeutic exercise versus manual therapy and therapeutic exercise alone
- Both treatment methods resulted in statistically significant and clinically meaningful improvements in current and average 24-hour pain on the VAS immediately after treatment up to 1-year post treatment among patients with shoulder and mechanical neck pain related to trigger points<sup>1,2</sup>
- There were no clinically meaningful differences, and only one statistically significant difference, in VAS scores between treatment methods at any time period post-treatment in either study<sup>1,2</sup>

### CLINICAL BOTTOM LINE

Trigger point dry needling in combination with non-invasive manual therapy and therapeutic exercise is not more effective than non-invasive techniques alone in reducing pain severity in patients with myofascial trigger points causing shoulder or neck pain in the short or long term. Dry needling is not justified to be included as a part of the first-line treatment strategy for myofascial trigger points, unless there are other evidence-based indications related to other impairments that were not explored in this CAT.

***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor***

*The above information should fit onto the first page of your CAT*

## SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	Intervention (or Assessment)	Comparison	Outcome(s)
Adult*, myofascial, myofascial pain, myofascial pain syndrome, MPS, myofascial trigger point*, trigger point*, TP, TrP	Trigger point*, TP, TrP, needl*, dry needl*, DN, TPDN, TrPDN, TrP DN, trigger point needl*, trigger point dry needl*	Manual therap*, MT, trigger point manual therap*, TPMT, TrPMT, TrP MT, stretch*, massag*, tissue massag*, soft tissue massag*, pressure, ischemic pressure, compression, ischemic compression, fascial release, myofascial release, MFR, transverse friction, transverse friction massag*, TFM, mobiliz*, tissue mobiliz*, soft tissue mobiliz*, manip*, tissue manip*, soft tissue manip*, non-thrust, non-thrust manip*, thrust, thrust manip*	Pain, pain rat*, pain sever*, pain reduc*, Visual Analogue Scale, VAS

### Final search strategy (history):

Show your final search strategy (full history) from PubMed. Indicate which "line" you chose as the final search strategy.

PubMed and Cochrane Library:

- Adult\* AND (myofascial OR myofascial pain OR myofascial pain syndrome OR MPS OR myofascial trigger point\* OR trigger point\* OR TP OR TrP)
- ((Trigger point\* OR TP OR TrP) AND (needl\* OR dry needl\* OR DN)) OR TPDN OR TrPDN OR TrP DN OR trigger point needl\* OR trigger point dry needl\*
- (Manual therap\* OR MT OR trigger point manual therap\* OR TPMT OR TrPMT OR TrP MT) OR stretch\* OR (massag\* OR tissue massag\* OR soft tissue massag\*) OR (pressure OR ischemic pressure) OR (compression OR ischemic compression) OR (fascial release OR myofascial release OR MFR) OR (transverse friction OR transverse friction massag\* OR TFM) OR (mobiliz\* OR tissue mobiliz\* OR soft tissue mobiliz\*) OR (manip\* OR tissue manip\* OR soft tissue manip\*) OR (non-thrust OR non-thrust manip\*) OR (thrust OR thrust manip\*)
- (Pain OR pain rat\* OR pain sever\* OR pain reduc\*) AND (Visual Analogue Scale OR VAS)
- #1 AND #2 AND #3 AND #4**

CINAHL:

- Adult\* AND (myofascial OR myofascial pain OR myofascial pain syndrome OR MPS OR myofascial trigger point\* OR trigger point\* OR TP OR TrP)
- ((Trigger point\* OR TP OR TrP) AND (needl\* OR dry needl\* OR DN)) OR TPDN OR TrPDN OR TrP DN OR trigger point needl\* OR trigger point dry needl\* (0 results)
- ((Trigger point\* OR TP OR TrP) AND (needl\* OR dry needl\*)) OR TPDN OR TrPDN OR TrP DN OR trigger point needl\* OR trigger point dry needl\* (0 results)
- ((Trigger point\* OR TP OR TrP) AND (needl\* OR dry needl\* OR DN)) OR TPDN OR TrPDN OR trigger point needl\* OR trigger point dry needl\* (587 results)
- ((Trigger point\* OR TP OR TrP) AND (needl\* OR dry needl\*)) OR TPDN OR TrPDN OR trigger point needl\* OR trigger point dry needl\* (580 results)
- (Manual therap\* OR MT OR trigger point manual therap\* OR TPMT OR TrPMT OR TrP MT) OR stretch\* OR (massag\* OR tissue massag\* OR soft tissue massag\*) OR (pressure OR ischemic pressure) OR (compression OR ischemic compression) OR (fascial release OR myofascial release OR MFR) OR (transverse friction OR transverse friction massag\* OR TFM) OR (mobiliz\* OR tissue mobiliz\* OR soft tissue mobiliz\*) OR (manip\* OR tissue manip\* OR soft tissue manip\*) OR (non-thrust OR non-thrust manip\*) OR (thrust OR thrust manip\*)
- (Pain OR pain rat\* OR pain sever\* OR pain reduc\*) AND (Visual Analogue Scale OR VAS)
- #1 AND #4 AND #6 AND #7**

In the table below, show how many results you got from your search from each database you searched.

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
PubMed	56 results	<p>RCT, systematic review, or meta-analysis only (39 results)</p> <p>Systematic review or meta-analysis only (1 result)</p> <p>Published in the last 10 years (45 results)</p> <p>Published in the last 5 years (26 results)</p> <p>RCT, systematic review, or meta-analysis only published in the last 10 years (32 results)</p> <p>RCT, systematic review, or meta-analysis only published in the last 5 years (17 results)</p>
CINAHL	33 results	<p>RCT, systematic review, or meta-analysis only (16 results)</p> <p>Systematic review or meta-analysis only (2 results)</p> <p>Published in the last 10 years (27 results)</p> <p>Published in the last 5 years (15 results)</p> <p>RCT, systematic review, or meta-analysis only published in the last 10 years (16 results)</p> <p>RCT, systematic review, or meta-analysis only published in the last 5 years (11 results)</p>
Cochrane Library	16 results	<p>Published in the last 10 years (14 results)</p> <p>Published in the last 5 years (10 results)</p>

#### INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
<ul style="list-style-type: none"> <li>Published in English only</li> <li>Human subjects only</li> <li>Adult subjects 18+ years old</li> <li>Subjects have trigger points</li> <li>Subjects treated with trigger point dry needling alone or in combination with other interventions</li> <li>Comparison made between trigger point dry needling alone or in combination with other interventions and other manual therapy techniques</li> <li>Study examines pain and VAS used as an outcome measure</li> </ul>
Exclusion Criteria
<ul style="list-style-type: none"> <li>Published in a language other than English</li> <li>Non-human subjects</li> <li>Case studies</li> <li>Children or adolescent subjects &lt;18 years old</li> <li>Subjects do not have trigger points</li> </ul>

- Acupuncture performed (intervention must be described as dry needling)
- Different dry needling method performed (not trigger point dry needling)
- No manual therapy intervention provided (no intervention or placebo or sham-intervention as only comparison)
- Study does not examine pain or use VAS as outcome measure

## RESULTS OF SEARCH

### Summary of articles retrieved that met inclusion and exclusion criteria

*For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).*

Author (Year)	Risk of bias (quality score)*	Level of Evidence**, ***	Relevance	Study design
Ziaefar et al. (2019) <sup>3</sup>	PEDro: 5/10	Level 3	High	Randomized control trial (RCT)
Yeganeh et al. (2016) <sup>4</sup>	PEDro: 4/10	Level 3	High	RCT
Lew et al. (2021) <sup>5</sup>	AMSTAR 2: Yes: 9 items, 4 critical items Partial yes: 2 items, 1 critical item No: 5 items, 2 critical items Overall confidence in results: Critically low	Level 1	High	Systematic review and meta-analysis of RCTs
Jalilipanah et al. (2021) <sup>6</sup>	PEDro: 4/10	Level 3	High	RCT
Cerezo-Téllez et al. (2016) <sup>7</sup>	PEDro: 6/10	Level 2	High	RCT
Ekici et al. (2021) <sup>8</sup>	PEDro: 5/10	Level 3	High	RCT
Pérez-Palomares et al. (2017) <sup>1</sup>	PEDro: 8/10	Level 2	Moderate	RCT
Gattie et al. (2021) <sup>2</sup>	PEDro: 9/10	Level 2	Moderate	RCT

\*Indicate tool name and score

\*\*Use Portney Table 36-1: Summary of Levels of Evidence (2020). If downgraded, indicate reason why.

\*\*\* RCTs were downgraded from Level 2 to Level 3 evidence, indicating a study with less rigorous design, if its PEDro score fell below the cut-off of 6-8/10, which is considered a "good" score.<sup>9</sup> All RCTs that were downgraded to Level 3 evidence have PEDro scores that fall in the "fair" category.<sup>9</sup>

## BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

- The 2017 RCT by Pérez-Palomares et al.<sup>1</sup> was identified as one of the best pieces of evidence regarding my selected PICO question. This RCT examined the effectiveness of trigger point dry needling in addition to an evidence-based individualized physical therapy treatment plan compared to the treatment plan alone in reducing shoulder pain in patients with myofascial trigger points. The purpose of the study was similar to my PICO question, in that it addressed the population, intervention, and outcome of interest.

The comparison provided in this study had reduced relevance to my PICO question, as it included not only manual therapy techniques but also exercise. However, the comparison examined is realistic and would be more likely to be performed in a physical therapy plan of care for this patient population than manual therapy techniques alone. Additionally, the RCT is considered Level 2 evidence and has a good PEDro score, indicating that the results are trustworthy. The only methodological flaws of this study were the failures to blind subjects and therapists to interventions, which is not typically feasible in the completion of physical therapy intervention studies. Therefore, this RCT was selected as a piece of best evidence to address my PICO question because of its high quality and relevance to my PICO question and PT practice in general.

- The 2021 RCT by Gattie et al.<sup>2</sup> was also identified as one of the best pieces of evidence regarding the selected PICO question. This RCT examined the effectiveness of trigger point dry needling in addition to a multi-modal treatment program compared to the treatment program and sham needling in improving disability and pain in patients with mechanical neck pain. The purpose of the study was similar to my PICO question, in that it addressed the population, intervention, and outcome of interest. Similar to the other selected study, the comparison provided in this study had reduced relevance to my PICO question, as it included not only manual therapy techniques but also exercise. Again, because this comparison is one that could be realistically seen in PT treatment of mechanical neck pain, with the exception of sham needling, this was not considered a barrier to selection. This RCT was also considered Level 2 evidence and has an excellent PEDro score. The only methodological flaw of this study was the failure to blind therapists to interventions. Therefore, this RCT was also selected as a piece of best evidence to address my PICO question because of its high quality and relevance to my PICO question and PT practice in general.

## SUMMARY OF BEST EVIDENCE

### (1) Description and appraisal of (Contribution of Dry Needling to Individualized Physical Therapy Treatment of Shoulder Pain: A Randomized Clinical Trial) by (Pérez-Palomares et al., 2017)<sup>1</sup>

<b>Aim/Objective of the Study/Systematic Review:</b>
The aim of this study was to determine how effective dry needling, in addition to an evidence-based individualized physical therapy treatment plan, is in improving shoulder pain in patients with myofascial trigger points compared to the treatment plan alone.
<b>Study Design</b>
[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]
Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.
This study was a multi-center, parallel, randomized control trial. Participants were randomly assigned by an independent researcher to either the intervention or control group using a computer based random number generator. The independent researcher concealed the allocation. While the study participants and physical therapists were unable to be blinded, the individual who performed all assessments was blinded to group allocation. Patients were assessed prior to beginning treatment, immediately after treatment, and 3 months after treatment. Due to the low number of subject attrition over the course of the study, the worst-observation-carried-forward method was applied to missing data for the intention to treat analysis. Statistical significance was defined as $p < 0.05$ .
<b>Setting</b>
[e.g., locations such as hospital, community; rural; metropolitan; country]
Interventions of this study were completed in several outpatient physical therapy practices in Zaragoza, Spain.
<b>Participants</b>
[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]
Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

132 patients with non-specific shoulder pain were recruited from 5 primary care centers in Zaragoza, Spain to ensure study reliability and screened for study eligibility by participating physical therapists. 120 patients met the inclusion and exclusion criteria and were enrolled in the study. Inclusion criteria included being 18 years or older in age, diagnosed with non-specific shoulder pain consistent with rotator cuff tendinopathy or subacromial impingement syndrome, and having greater than 50% range of motion in shoulder flexion and abduction. Exclusion criteria included prior surgery for subacromial syndrome, symptom onset following an injury suggesting an alternative diagnosis, glenohumeral instability, symptoms suggestive of systemic disease, presence of other conditions that may interfere with completion of therapy or result in harm to the patient, and inability or unwillingness to attend therapy. 62 individuals were randomly assigned to the control group, and 57 to the intervention group. The control and intervention groups displayed baseline comparability, with no significant differences in demographic or clinical variables present. Both groups displayed similar scores on baseline outcomes measures and demonstrated similar rates of pathology diagnosed via ultrasound or MRI. Mean age in the control group was  $54.32 \pm 11.45$  years, and in the intervention group was  $52.74 \pm 11.81$  years. There were 28 males and 35 females in the control group, and 17 males and 40 females in the intervention group. 117 patients completed all treatment sessions, with 2 patients in the control group and 1 in the intervention group lost to follow up, and 109 patients completed the 3 month follow up assessments, with 6 patients in the control group and 5 in the intervention group lost to follow up.

### **Intervention Investigated**

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

#### *Control*

The control group in this study received evidence-based physical therapy interventions personalized to their impairments. Patients in the control group were examined by a physical therapist with thorough passive and active assessments performed in the affected shoulder. Manual therapy techniques and exercises, including articular gliding, joint range of motion, stretching, isometric exercises, exercises for neuromuscular re-education and scapular control, and postural exercises, were prescribed to patients based on their individual physical evaluation. Patients attended a total of 10 physical therapy sessions, with two sessions per week, each 30 minutes in duration.

Physical therapists that provided treatment to the control group had over 5 years of experience, including in treating trigger points. They also were trained over 4 sessions by an expert in dry needling to ensure protocol standardization.

#### *Experimental*

The intervention group in this study received evidence-based physical therapy interventions personalized to their impairments in addition to trigger point dry needling. Patients in the intervention group were examined by a physical therapist with thorough passive and active assessments performed in the affected shoulder. Physical therapists also examined patients for the presence of active myofascial trigger points in their supraspinatus, infraspinatus, subscapularis, teres minor, and deltoid muscles. Manual therapy techniques and exercises, including articular gliding, joint range of motion, stretching, isometric exercises, exercises for neuromuscular re-education and scapular control, and postural exercises, were prescribed to patients based on their individual physical evaluation. Identified trigger points were dry needled using a fast in and out technique and acupuncture needles measuring  $0.25 \times 25$  mm,  $0.30 \times 50$  mm, and  $0.30 \times 75$  mm. Patients attended a total of 10 physical therapy sessions, with two sessions per week, each 30 minutes in duration in which they received their personalized treatment. Patients in the intervention group also participated in a total of 3 dry needling sessions, in the first, fourth, and seventh sessions to allow 8 days between each dry needling session.

Physical therapists that provided treatment to the intervention group had over 5 years of experience, including in treating trigger points. They also were trained over 4 sessions by an expert in dry needling to ensure protocol standardization.

### **Outcome Measures**

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

Patients were assessed prior to treatment, immediately after treatment, and 3 months after treatment by an evaluator blind to group allocation.

Demographic information was collected at baseline only, including age, sex, job, medical history, history of present illness, and medications.

The primary outcome measure was patient reported pain and was quantified using the visual analogue scale (VAS). The VAS is a scale with a horizontal line with two vertical lines at either end marked as "no pain"

which equals a score of 0 and “maximum pain experience” which equals a score of 10, with higher scores indicating higher pain. A clinically meaningful improvement of pain using the VAS is 1.5 points.

Secondary outcome measures include joint range of motion, the Constant-Murley score, and number of active trigger points. Glenohumeral flexion and abduction joint range of motion was measured using a digital inclinometer in degrees. Glenohumeral internal and external rotation range of motion was assessed using a subscale of the Constant-Murley score. The Constant-Murley score was used to assess function, and ranges from 0-100 points. It has subscales for pain (0-15 points), everyday activities (0-20 points), mobility (40 points), and strength (25 points), with higher scores indicating higher function. Myofascial trigger points were identified in the muscles stated previously using Travell and Simon’s diagnostic criteria.

One additional outcome, nocturnal pain, self-reported as either “yes” or “no” was also assessed.

### Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.]

In regards to the primary outcome of pain as measured by the VAS, both groups demonstrated significant and clinically meaningful (>1.5 point) improvements in pain immediately after the treatment and 3 months after the treatment compared to baseline. There was a statistically significant 0.86-point (confidence interval 0.06 to 1.67 points) difference in pain on the VAS immediately after treatment between the groups in favor of the intervention. However, this difference was not clinically meaningful. No other statistically significant or clinically meaningful between group differences in VAS score were observed.

Table 1a. VAS Mean Scores and Standard Deviation

	Baseline score	Post-treatment score	3 months post-treatment score
Control	6.75 ± 1.50	4.71 ± 2.28	3.59 ± 2.61
Intervention	6.58 ± 1.52	3.81 ± 2.20	3.00 ± 2.44

Table 1b. VAS Mean Within and Between Group Differences (95% Confidence Interval)

	Post-treatment score	3 months post-treatment score
Within control group (compared to baseline)	2.04 (1.44, 2.63)*, **	3.16 (2.55, 3.77)*, **
Within intervention group (compared to baseline)	2.77 (2.08, 3.46)*, **	3.58 (2.82, 4.34)*, **
Between groups	0.86 (0.06, 1.67)**	0.52 (-0.37, 1.42)

\*p<0.001

\*\*Statistically significant (P<0.05)

In regards to secondary outcomes, both groups demonstrated significant improvements in internal rotation range of motion as measured by the Constant-Murley score, and number of active trigger points both immediately after the treatment and 3 months after the treatment. There was a statistically significant improvement in shoulder external rotation range of motion in the control group only. Changes in Constant-Murley scores, although statistically significant, were not clinically meaningful in either group, as neither achieved a mean 17-point change. There were no statistically significant or clinically meaningful between group differences in range of motion, function, or number of trigger points 3 months after treatment.

In regards to the additional outcome of nocturnal pain, both groups demonstrated improvements both immediately after treatment and 3 months after treatment compared to baseline. There was a slight between group difference immediately after treatment, in which the intervention group demonstrated greater improvement (odds ratio = 0.41; confidence interval, 0.17, 0.99), though this was not maintained 3 months after treatment.

### Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors of this study concluded that dry needling in addition to an individualized, evidence-based physical therapy treatment plan was no better than the treatment plan alone in improving pain, range of motion, function, and reduction in number of active trigger points in patients with non-specific shoulder pain. These authors concluded that dry needling is therefore not justified as an additional method to manage outcomes in this patient population.

### Critical Appraisal

#### Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

This study demonstrated excellent interval validity due to the rigorous research design. This study was a randomized control trial, which is considered Level 2 evidence, and demonstrated a good PEDro score of 8/10. This study selected participants from multiple locations, and randomly assigned participants to groups through concealed allocation to improve validity. This study blinded assessors of outcomes to minimize bias. Therapists also performed all interventions in a very standardized manner and received training in order to do so. This study also considered attrition by performing an intention to treat analysis. The only threats to internal validity identified were that participants and therapists were unable to be blinded to results, which is very difficult to do in physical therapy studies. This study also demonstrates high external validity, as patients who were recruited represent a broad sample and an adequate number of patients were included in the study to improve generalizability. Additionally, interventions performed in this study were similar to those that would normally be performed in physical therapy practice, improving transferability of these results to a clinical setting. The authors identified several strengths and limitations of this study. Strengths of this study include that it had an appropriate sample size, was representative of actual patient populations, and followed patients over a time period of three months. Limitations of this study include that patients were included in this study based on clinical diagnosis from a primary care provider instead of radiological diagnosis. Additional strengths include the use of a personalized, comprehensive, and evidence based physical therapy treatment plan consistent with current clinical practice and standardization of study procedures. Additional limitations include no inclusion of long term follow up to examine long-term effects of treatment. Overall, evidence provided by this study is of high quality and very relevant to current clinical practice.

#### Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Both the control and the intervention groups demonstrated statistically significant and clinically meaningful decreases in VAS scores immediately after treatment and 3 months after treatment compared to baseline. P values for each of these differences was  $<0.001$ , indicating extremely low probability that these observations were due to chance. VAS scores were decreased by approximately 2 points for each group immediately after treatment, and 3 points 3 months after treatment, which exceeds the minimally clinically importance difference of 1.5-point change on the VAS.

The mean VAS scores of the intervention group were lower than the control group both immediately after treatment and 3 months after treatment, with the difference of 0.86 points being statistically significant immediately after treatment. However, the difference of 0.52 points was not statistically significant at 3 months post-treatment. The authors of this study determined what sample size would produce a power of 90% a priori, and conducted this study using an appropriate sample size. This indicates that lack of statistical significance was likely not due to lack of power, and may truly be due to lack of difference in treatment effect between interventions. Additionally, differences of 0.86 and 0.52 points do not meet the criteria for a clinically meaningful difference on the VAS, which is 1.5 points. Therefore, while differences in mean scores exist and are significant immediately after treatment, they are not clinically meaningful.

Because such a rigorous study design was used, and strengths of this study outweigh limitations, these results have clinical importance.

#### Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]



The findings of this study are highly relevant and applicable to my clinical question and scenario. This study examined interventions for adults with myofascial trigger points, similar to the patients in my clinical scenario. The study also examined dry needling in combination with current best-practice physical therapy interventions versus current interventions alone, in accordance with my clinical question. Finally, this study examined my outcome of interest, which was patient pain as measured by the VAS. Because this study addressed all components of my clinical question, the results could certainly be applied to my clinical scenario. Additionally, because the interventions provided in this study are extremely similar to interventions that would typically be used in physical therapy practice, including manual therapy and therapeutic exercise, it is feasible and practical that the interventions used in this study in the control group could be used in actual clinical practice. Furthermore, it is practical and feasible that dry needling not be performed in clinical practice, as clinicians may have to have additional training, doctor's orders, or may be legally prohibited from performing dry needling based on clinic location.

**(2) Description and appraisal of (Dry Needling Adds No Benefit to the Treatment of Neck Pain: A Sham-Controlled Randomized Clinical Trial With 1-Year Follow-up) by (Gattie et al., 2021)<sup>2</sup>**

**Aim/Objective of the Study/Systematic Review:**

The aim of this study was to determine how effective dry needling, in addition to a physical therapy treatment plan including manual therapy and exercise, is in improving disability and pain among patients with mechanical neck pain in the short- and long-term compared to sham needling and the treatment plan alone.

**Study Design**

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

This study was a randomized control trial. Participants were randomly assigned by a research assistant to either the intervention or control group using a computer based random number generator prior to the study. The research assistant concealed the allocation by placing the group assignment in a sealed opaque envelope in each participant's folder. While the physical therapists were unable to be blinded, the individual who performed all assessments was blinded to group allocation. Patients were also blinded to their group allocation, as sham needling was used as a control. Patients baseline data was obtained prior to beginning treatment, and outcomes were assessed 4 weeks, 6 months, and 1 year after treatment. An intention-to-treat analysis was performed. Statistical significance was defined as  $p < 0.05$ .

**Setting**

[e.g., locations such as hospital, community; rural; metropolitan; country]

Interventions of this study were completed in Concord Hospital (Concord, NH) and Franciscan Health (Indianapolis, IN) outpatient physical therapy clinics.

**Participants**

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

Patients with acute, subacute, or chronic mechanical neck pain were recruited from Concord Hospital (Concord, NH) and Franciscan Health (Indianapolis, IN) outpatient physical therapy clinics and screened for study eligibility. 77 patients met the inclusion and exclusion criteria and were enrolled in the study. Inclusion criteria included being 18 years or older in age, having a chief complaint of neck pain, and a Neck Disability Index score greater than 10 points. Exclusion criteria included presence of red flags, use of blood thinners, history of recent (<6 weeks) whiplash injury, symptoms indicating central nervous system involvement, 2 or more signs and symptoms of nerve root compression, prior cervical or thoracic spine surgery, receiving workers' compensation or involved in legal action regarding their neck pain, language barriers preventing ability to complete questionnaires, and disinterest or inability to participate in all sessions. 37 individuals were randomly assigned to the control group, and 40 to the intervention group. The control and intervention

groups displayed baseline comparability, with no significant differences in demographic or clinical variables present. Both groups displayed similar scores on baseline outcomes measures, though participants in the needling group had an average duration of symptoms of  $23.38 \pm 51.35$  months compared to  $11.41 \pm 16.57$  months in the control group. Mean age in the control group was  $48.22 \pm 15.18$  years, and in the intervention group was  $45.28 \pm 13.23$  years. There were 32 females in the control group, and 29 females in the intervention group, representing 79% of all participants. 68 patients completed the 4-week post-treatment assessment, 60 completed the 6-month post-treatment assessment, and 58 completed the 1-year post-treatment assessment, with 7 patients in the control group and 12 in the intervention group lost to follow up.

### **Intervention Investigated**

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

#### *Control*

The control group in this study received manual therapy, therapeutic exercise, and sham dry needling. Manual therapy was performed to address cervical and thoracic spine joint mobility. Therapeutic exercise focused on improving deep neck flexor and scapular musculature performance. Sham dry needling was performed in cervical and thoracic spine musculature, including the trapezius, levator scapulae, splenius capitis, semispinalis, spinalis capitis, multifidus, and suboccipital muscles. Therapists sham dry needled at least 6 different sites in these muscles, though could needle up to 10, to simulate the actual dry needling intervention. Park sham acupuncture needles were used during sham therapy interventions, as they cause a pricking sensation when pressed against the skin that simulates being penetrated by a needle without the needle actually penetrating skin. Patients attended a total of 7 physical therapy sessions over a maximum of 4 weeks. Each session lasted 45 minutes, with 15 minutes each devoted to manual therapy, exercise, and sham dry needling.

Seven physical therapists provided treatment to the control group and had an average of 12 years of experience, including over 6 years on average of performing dry needling. They also attended a 2-hour training session in order to standardize application of manual therapy, exercise, dry needling, and sham dry needling.

#### *Experimental*

The intervention group in this study received manual therapy, therapeutic exercise, and dry needling. Manual therapy was performed to address cervical and thoracic spine joint mobility. Therapeutic exercise focused on improving deep neck flexor and scapular musculature performance. Dry needling of trigger points in cervical and thoracic spine musculature, including the trapezius, levator scapulae, splenius capitis, semispinalis, spinalis capitis, multifidus, and suboccipital muscles was also performed. Therapists dry needled at least 6 different sites in these muscles, though could needle up to 10, using an in and out technique based on prevalence of trigger points. Patients attended a total of 7 physical therapy sessions over a maximum of 4 weeks. Each session lasted 45 minutes, with 15 minutes each devoted to manual therapy, exercise, and dry needling.

Seven physical therapists provided treatment to the intervention group and had an average of 12 years of experience, including over 6 years on average of performing dry needling. They also attended a 2-hour training session in order to standardize application of manual therapy, exercise, dry needling, and sham dry needling.

### **Outcome Measures**

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

Patients were assessed prior to treatment, 4 weeks after treatment, 6 months after treatment, and 1 year after treatment by an evaluator blind to group allocation.

Demographic information was collected at baseline only.

The primary outcome measure was disability as measured by the Neck Disability Index (NDI). The NDI ranges from 0-100 points, with higher scores indicating worse function.

Secondary outcome measures include current and 24-hour average pain as rated on the VAS, patient-perceived improvement in function as measured by the global rating of change scale (GROC), and patient perception of dry needling. The VAS is a scale with a horizontal line with two vertical lines at either end marked as "no pain" which equals a score of 0 and "maximum pain experience" which equals a score of 10, with higher scores indicating higher pain. A clinically meaningful improvement of pain using the VAS is 1.5 points.<sup>1</sup> The GROC measures change in function by asking individuals to describe their function as "a very great deal worse," "about the same," or "a very great deal better," which correlates with scores of -7, 0, and +7 respectively. To determine patient perception about dry needling, patients were asked "Do you think you

received the real dry needling intervention?" Patient response of yes, no, or completely unsure were recorded 4 weeks post-treatment.

### Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

In regards to the primary outcome measure of NDI score, both groups demonstrated statistically significant and clinically meaningful improvements at all follow-up assessments compared to baseline ( $F=124.20$ ,  $P<0.001$ ). However, there was no significant group by time interaction ( $F=0.42$ ,  $P=0.69$ ). There were no significant differences between group means in NDI scores at any point of measurement (4 weeks:  $p=0.93$ , 6 months:  $p=0.32$ , 1 year:  $p=0.85$ ).

In regards to the secondary outcome measures of current and 24h pain, both groups demonstrated statistically significant and clinically meaningful improvements at all follow-up assessments compared to baseline (current pain:  $F=64.28$ ,  $P<.001$ ; 24h pain:  $F=76.69$ ,  $P<.001$ ). However, there was no significant group by time interaction (current pain:  $F=1.04$ ,  $p=0.37$ ; 24h pain:  $F=0.01$ ,  $p=0.10$ ). There were no significant differences between group means in current or 24h pain scores at any point of measurement, as shown in the graphs below.

Table 2a. VAS Current Pain Mean Scores and Standard Deviation

	Baseline score	4 weeks post treatment score	6 months post treatment score	1-year post treatment score
Control	3.85 ± 2.23	1.61 ± 1.88	1.26 ± 1.52	1.37 ± 1.84
Intervention	4.58 ± 1.86	1.67 ± 1.51	2.00 ± 1.83	1.69 ± 1.89

Table 2b. VAS Current Pain Mean Within and Between Group Differences and Standard Deviation/95% Confidence Interval/p-value

	4 weeks post treatment score	6 months post treatment score	1-year post treatment score
Within control group (compared to baseline)	2.24 ± 2.60	2.59 ± 2.20	2.47 ± 2.17
Within intervention group (compared to baseline)	2.91 ± 1.86	2.58 ± 2.38	2.89 ± 2.22
Between groups	0.05 (-0.83, 0.72) P=0.891	0.73 (-1.50, 0.04) P=0.061	0.32 (-1.17, 0.53) P=0.426

Table 2c. VAS 24h Pain Mean Scores and Standard Deviation

	Baseline score	4 weeks post treatment score	6 months post treatment score	1-year post treatment score
Control	5.8 ± 2.34	2.23 ± 2.34	1.85 ± 2.21	1.77 ± 2.35
Intervention	6.06 ± 2.00	2.57 ± 2.31	2.21 ± 2.24	2.11 ± 2.30

Table 2d. VAS 24h Pain Mean Within and Between Group Differences and Standard Deviation/95% Confidence Interval/p-value

	4 weeks post treatment score	6 months post treatment score	1-year post treatment score

Within control group (compared to baseline)	3.57 ± 3.08	3.95 ± 2.97	4.03 ± 3.16
Within intervention group (compared to baseline)	3.49 ± 2.94	3.85 ± 3.02	3.95 ± 3.00
Between groups	0.33 (-1.39, 0.72) P=0.530	0.36 (-1.37, 0.66) P=0.507	0.33 (-1.37, 0.73) P=0.531

In regards to the secondary outcome measure of GROC scores, there were no significant differences between group means at any point of measurement (4 weeks: p=0.880, 6 months: p=0.658, 1 year: p=0.645).

In regards to the secondary outcome measure of patient perception of dry needling, at four-weeks post-treatment, 79% of all participants (25 participants in the control group and 29 in the intervention group) answered "yes" to the question "Do you think you received the real dry needling intervention?" 21% of all participants (9 in the control group and 5 in the intervention group) answered "completely unsure" to the same question. No participants in either group responded "no" to the same question, indicating that treatments were indistinguishable between the intervention and control groups.

### Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors of this study concluded that dry needling in addition to a physical therapy treatment plan consisting of manual therapy and exercise was no better than the treatment plan alone in improving disability or pain in patients with mechanical neck pain in the short- or long-term. These authors concluded that dry needling should not be used in the first-line management strategy of mechanical neck pain.

### Critical Appraisal

#### Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

This study demonstrated excellent interval validity due to the rigorous research design. This study was a randomized control trial, which is considered Level 2 evidence, and demonstrated a good PEDro score of 9/10. This study selected participants from multiple locations, and randomly assigned participants to groups through concealed allocation to improve validity. This study blinded assessors of outcomes to minimize bias. Therapists also performed all interventions in a very standardized manner and received training in order to do so. This study also considered attrition by performing an intention to treat analysis. This study successfully blinded participants to group allocation by use of a sham needling control, which is difficult to perform in physical therapy intervention studies and strengthens internal validity. The only threat to internal validity identified was that therapists were unable to be blinded to results, which is also very difficult to do in physical therapy studies. This study also demonstrates high external validity, as patients who were recruited represent a broad sample and an adequate number of patients were included in the study to improve generalizability. Additionally, interventions performed in this study were similar to those that would normally be performed in physical therapy practice, improving transferability of these results to a clinical setting. The authors identified several strengths and limitations of this study. Strengths of this study include that treatment methods were consistent with typical physical therapy practice for the treatment of mechanical neck pain, and broad inclusion criteria was used to increase generalizability of study results. Another strength of this study was the use of the sham needling procedure, which was indistinguishable from the actual dry needling procedure according to patient perception of treatment. Limitations of this study include that therapists could only perform one dry needling technique, and there was variability between patients in regards to their treatment protocol. Additionally, the patients included in this study varied in age and chronicity of symptoms, which may have affected study results. Additional strengths include using a pre-determined algorithm to standardize treatment based on patient presentation, assessing outcomes over 1 year to determine long-term effects of treatment, and reporting on frequency of adverse effects experienced during the study. Additional limitations include dissimilarity of study interventions compared to clinical practice due to using an algorithm that may restrict clinician choice of treatment based on clinical expertise. Overall, evidence provided by this study is of high quality and very relevant to current clinical practice.

### Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Both the control and the intervention groups demonstrated clinically meaningful decreases in VAS scores 4 weeks, 6 months, and 1 year after treatment compared to baseline. Current VAS scores were decreased by approximately 2-3 points in both groups at each follow-up assessment, and 24h VAS scores were decreased by approximately 3-4 points in both groups at each follow-up assessment compared to baseline, which exceeds the minimally clinically importance difference of 1.5-point change on the VAS.

There were mean differences in current and 24h VAS scores between the control and intervention groups at all follow-up assessments, however none of these differences were statistically significant. The authors of this study determined what sample size would produce adequate power a priori, and conducted this study using an appropriate sample size. This indicates that lack of statistically significance was likely not due to lack of power, and may truly be due to lack of difference in treatment effect between interventions. Furthermore, mean differences in current VAS scores were 0.05, 0.73, and 0.32 points at 4 weeks, 6 months, and 1 year after treatment respectively. Mean differences in 24h VAS scores were 0.33 0.36, and 0.33 points at 4 weeks, 6 months, and 1 year after treatment respectively. These differences in VAS score do not meet the criteria for a clinically meaningful difference on the VAS, which is 1.5 points. Therefore, there were no statistically significant or clinically meaningful between group differences in VAS scores at any follow-up time frame.

Because such a rigorous study design was used, and strengths of this study outweigh limitations, these results have clinical importance.

### **Applicability of Study Results**

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

The findings of this study are highly relevant and applicable to my clinical question and scenario. This study examined interventions for adults with myofascial trigger points, similar to the patient in my clinical scenario. The study also examined dry needling in combination with current best-practice physical therapy interventions versus current interventions alone, in accordance with my clinical question. Finally, this study examined my outcome of interest as a secondary outcome, which was patient pain as measured by the VAS. Because this study addressed all components of my clinical question, the results could certainly be applied to my clinical scenario. Additionally, because the interventions provided in this study are extremely similar to interventions that would typically be used in physical therapy practice, including manual therapy and therapeutic exercise, it is feasible and practical that these interventions used in this study in the control group could be use in actual clinical practice. However, it is not feasible nor practical to use sham dry needling in clinical practice, which was an intervention applied within the control group. Furthermore, it is practical and feasible that dry needling not be performed in clinical practice, as clinicians may have to have additional training, doctor's orders, or may be legally prohibited from performing dry needling based on clinic location.

## **SYNTHESIS AND CLINICAL IMPLICATIONS**

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

Both pieces of best evidence reviewed for this CAT found that trigger point dry needling in addition to non-invasive manual therapy and therapeutic exercise resulted in statistically significant and clinically meaningful improvements in patient shoulder or neck pain in the short- or long-term compared to baseline. However, these improvements were not superior to those observed among patients who received non-invasive techniques alone. Pérez-Palomares et al. found that both patients who received dry needling plus non-invasive techniques and patients who only received non-invasive techniques demonstrated reductions in pain both immediately and 3 months after 10 physical therapy sessions that exceeded the minimally clinically importance difference of 1.5 points on the VAS.<sup>1</sup> However, authors did not find differences between the groups at either time point that were both statistically significant and clinically meaningful, indicating that the addition of dry needling did not improve outcomes among patients who received manual therapy and therapeutic exercise to treat non-specific shoulder pain.<sup>1</sup> Gattie et al. similarly found that patients who received dry needling plus non-invasive techniques and patients who received non-invasive techniques and sham needling also both demonstrated reductions in pain greater than 1.5 points on the VAS 4 weeks, 6 months, and 1 year after 7 physical therapy sessions.<sup>2</sup> Additionally, authors also found that there were no statistically significant or clinically meaningful differences in pain between the two groups at any point in time after treatment, indicating that the addition of dry needling to other non-invasive treatments is again not beneficial in reducing mechanical neck pain.<sup>2</sup> Both studies concluded that dry needling should not be

considered as a primary treatment for trigger point related neck and shoulder pain, as manual therapy and therapeutic exercise alone can cause significant, meaningful, and lasting reductions in pain.

Both studies demonstrated high internal and external validity by using strong study designs that reduce bias and including a variety of participants that are similar to patients seen in typical physical therapy practice. Both studies also included interventions that are evidence-based, acceptable, and feasible to complete in clinical practice, with the exception of the sham dry needling that was performed as a part of the control group in the latter study. Therefore, study results could readily be applied to current clinical practice.

While these two studies were of high quality and therefore have trustworthy results, more high quality RCTs, systematic reviews, and meta-analyses need to be completed to improve confidence in these results. Lower quality studies that were preliminarily included in this CAT reported conflicting evidence on whether or not trigger point dry needling is superior to some treatment interventions.<sup>3-8</sup> Several of these studies found that trigger point dry needling alone or in combination with other treatments was superior at decreasing pain compared to other treatments alone, including trigger point compression, muscle energy techniques, and passive stretching.<sup>3,4,7</sup> However, several studies also refuted the superiority of trigger point dry needling, particularly when compared to non-specific trigger point manual therapy techniques, muscle energy techniques, and deep friction massage.<sup>5,6,8</sup> As more research is performed, clarity will hopefully be improved on which interventions are most effective at reducing pain in patients with myofascial trigger points.

Based on the best available evidence reviewed in this CAT, dry needling in combination with other non-invasive treatments is not superior to non-invasive treatments alone in reducing short- or long-term pain among patients with trigger point related shoulder and neck pain. Dry needling adds no pain-relieving benefit when performed in combination with manual therapy and therapeutic exercises for shoulder and neck pain, and should not be used in addition to these treatments unless evidence exists that other concurrent impairments not addressed in this CAT may improve after dry needling.

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[List all references cited in the CAT]

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