Effects of Subscapularis Muscle Dry Needling on clinical symptom improvement in People with Frozen Shoulder: A Randomized Controlled Trial Protocol

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INTRODUCTION

Frozen shoulder, a term that was introduced by Codman in 1934, referred to a condition with symptoms in the shoulder region, especially in the deltoid muscle insertion, with a slow onset that inability to sleep on the affected side is considered as the chief complaint. Frozen shoulder is a common musculoskeletal problem, affecting 2 to 5 percent of the population (1, 2). This condition is accompanied by a gradual and spontaneous increase in pain and a decrease in active and passive range of motion (ROM) (3) mainly because of the formation of fibrosis tissue and shortening of the joint capsule and ligaments surrounding the glenohumeral (GH) joint (4, 5). Considering that the GH joint is involved in many daily activities, any complication, such as a frozen shoulder or tendonitis, which reduces the ROM and causes pain in this area, leads to severe restrictions (6).
The role of rotator cuff muscles, especially the subscapularis muscle, is crucial in the dynamic stability of the GH joint (7). The subscapularis muscle is one of the major muscles between rotator cuff muscles, which primarily acts as an internal rotator of the humerus (8, 9), but it also has a function in the GH joint flexion, abduction, and adduction (10, 11).

Although the frozen shoulder, according to its definition, is a capsular problem, the development of myofascial trigger points (MTrPs) in the rotator cuff muscles may aggravate its symptoms (4). MTrPs are “hyper-irritable points in the taut band of skeletal muscles or fascia which cause local sensitivity and referred pain” (11). MTrPs are classified as active and latent MTrPs: “active MTrP has spontaneous pain or pain in response to movement, stretch or compression, while latent MTrP is a sensitive spot with pain or discomfort in response to just compression” (12). The subscapularis MTrPs are usually considered key MTrPs in the frozen shoulder syndrome, which can cause pain at rest and during motion (10, 12). The referral pain pattern of subscapularis MTrPs is felt at the posterior side of the shoulder, which may extend to the scapula and elbow, even more distant areas like the dorsal part of the wrist (11). In people with shoulder pain, the presence of subscapularis MTrPs is often overlooked, which must be considered in the treatment plan (11). The initial symptoms of a frozen shoulder, including restricted shoulder movement, especially abduction, external rotation, and shoulder pain, are shared with the initial symptoms of active MTrPs of the subscapularis muscle. In many cases, they both can occur concurrently (11). After developing MTrPs in the subscapularis, other muscles in the shoulder region, like the long head of the biceps brachii, deltoïd (anterior portion), pectoralis major, teres major, and latissimus dorsi could develop MTrPs and the movement of the GH joint is severely limited in all planes (11).

Physiotherapy, as a conservative treatment, mainly suggests electrotherapy, hot packs, Laser, short-wave diathermy, ultrasound therapy, and manual mobilization. Dry needling (DN), as a new, effective, and minimally invasive method in the physiotherapy field is defined as “inserting the needle into the muscle to deactivate MTrPs via creating a response called the local twitch response (LTR)” (13). Besides of various interventions in treating of patients with frozen shoulder, ultrasonography is a reliable method in assessing MTrP characteristics (14, 15) and ultrasound guided dry needling is used in addition to conventional physiotherapy in patients with musculoskeletal disorders (16, 17). In some studies, the effects of subscapularis MTrPs deactivation on clinical symptoms of people with frozen shoulder have been investigated. According to a study that was conducted in 2019, it was stated that possibly eliminating the MTrPs of the subscapularis muscle with manual techniques may reduce the pain intensity and increase the ROM of the external rotation of the shoulder joint in people with chronic frozen shoulder. In 2021, a study evaluated the impact of DN as a therapeutic intervention on the MTrPs in the rotator cuff muscles of individuals with frozen shoulder, and it was demonstrated that DN could be effective in alleviating the intensity of pain, increasing ROM, and increasing pain tolerance in people with frozen shoulder (4). There were some limitations in the study, such as the absence of a control group and performing the DN technique on a group of muscles, (not specific muscle), which should be considered in the design of future studies.

To the best of our knowledge, evidence of the impact of DN on a frozen shoulder is limited (4, 18, 19). On the other hand, in these studies based on the presence of MTrPs at different muscles, interventions have been done on various muscles, and evidence on deactivating subscapularis MTrPs as an isolated muscle is limited. For this, the study aims to investigate the impact of subscapularis MTrPs-DN on improving pain, ROM of the GH joint, and intensity of upper limb functional disability in individuals with frozen shoulder.

Study goal and its hypothesis

The primary goal of the current study is to evaluate the impact of DN on MTrPs of the subscapularis muscle added to the conventional physiotherapy in comparison with conventional physiotherapy alone on pain intensity in the shoulder region and ROM in abduction, flexion, external rotation, and internal rotation, as well as pain pressure threshold (PPT) and upper limb functional disability. The study hypothesis is that the participants who receive MTrPs-DN during their treatment procedure would experience better improvement in the level of pain, ROM, PPT, and upper limb functional disability compared to those who receive just conventional physiotherapy.

METHODS

Study design

This protocol is for a randomized, single-blinded trial in which the outcome assessor is blinded to the interventions and will be conducted in a physiotherapy clinic related to the Tabriz University of Medical Sciences. Different items in this paper have been written according to the principles defined at the SPIRIT 2013 statement.

Ethical issues

This study was registered in the ethics committee with IR.TBZMED.REC.1402.013 code on 2023-03-06 (date of approval: March 06, 2023).
Experimental procedures

Participants
Participants are adults who will be referred to the physiotherapy clinic with a diagnosis of frozen shoulder and the existence of the subscapularis muscle MTrPs of the involved side. The complete eligibility criteria (inclusion and exclusion criteria) are listed in table I.

Preparation and treatment setting
Recruitment will begin by talking with people who will be referred to the physiotherapy clinic with a diagnosis of frozen shoulder; in case of eligibility confirmation, they will be informed about the study and its goals. Once they are acknowledged and still interested in participating, they will need to sign an informed consent form to be recruited in the study. Then, demographic information will be collected; there are six factors to consider: age, sex, height, weight, medication and physiotherapy history, and the affected shoulder.

Following the collection of the baseline data, 40 participants will be randomly recruited into intervention and control groups using the permuted block randomization method to avoid bias in the conclusion (20 patients for each group). Outcome measures include pain intensity, ROM of the glenohumeral joint (in flexion, abduction, internal and external rotation), upper limb functional disability, and pain pressure threshold. The outcome measures will be assessed twice by a blinded assessor, once at baseline and once after completion of the sessions. The Persian version of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire will be distributed and then collected during the 1st, 5th, and 10th sessions. Participants in both groups will receive ten treatment sessions which will be held on alternate days. The control group will receive conventional physiotherapy. The intervention group, simultaneously with the treatment of the control group, will receive three sessions of subscapularis MTrP-DN during the third, sixth, and ninth sessions. The trial schedule is shown in figure 1.

### Table I. Inclusion and exclusion criteria of the study.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged between 35 and 65 years</td>
<td>Skin problem at shoulder and scapula (6)</td>
</tr>
<tr>
<td>VAS at least 3 at subscapularis MTrPs while they compressed (25)</td>
<td>Antiplatelet therapy 3 days before starting of the study (6)</td>
</tr>
<tr>
<td></td>
<td>Corticosteroid injections in the shoulder area 3 months before starting the study (6)</td>
</tr>
<tr>
<td></td>
<td>History of cancer (6)</td>
</tr>
<tr>
<td></td>
<td>Needle phobia (6)</td>
</tr>
<tr>
<td></td>
<td>Positive subacromial entrapment tests (26)</td>
</tr>
<tr>
<td></td>
<td>Shoulder joint surgery or arthroscopy (6)</td>
</tr>
<tr>
<td></td>
<td>Cervical radiculopathy or any neurological damage in the upper limb (22)</td>
</tr>
<tr>
<td></td>
<td>Rheumatoid disease (22)</td>
</tr>
<tr>
<td></td>
<td>Pregnancy (27)</td>
</tr>
</tbody>
</table>

VAS: Visual Analogue Scale; MTrPs: Myofascial Trigger Points.
Performing assessment and treatment

The trial assessment is going to be performed by a blinded assessor, who is an expert physiotherapist (PT) with clinical experience. The treatment plan is going to be performed by another eligible PT who is certified in MTrP-DN and experienced in the treatment of musculoskeletal disorders.

Interventions

Trigger point diagnosis

The exact location of the subscapularis muscle MTrPs will be spotted by an expert PT according to Travel and Simons’ criteria (11): presence of 1) a taut band within the muscle, 2) a hyperirritable tender point in the taut band, 3) spontaneous pain, 4) local twitch response (LTR) after compression, and 5) a familiar referred pain in referral zone after irritating the tender point. For this purpose, the participant will be asked to lie in a supine position. The examiner moves the participant’s arm to 90 degrees of abduction. In the next step, the examiner takes the latissimus dorsi tendon with a pincer grip and marks the lateral border of the scapula with his/her fingertips. The examiner then slowly moves his/her fingertips downward to palpate the subscapularis muscle on the anterior side of the scapula. To locate the MTrP of the subscapularis muscle, which is placed in the upper portion of the lateral edge of the scapula, the examiner may go in an upward direction toward the coracoid process to palpate more fibers at the superior aspect and detect a taut band in the muscle (11). Sustained light to moderate pressure, in the presence of the MTrP, will reproduce pain at the posterior portion of the shoulder and scapula.

Control group

Participants in this group will receive conventional physiotherapy during 10 sessions on alternate days by an expert PT. Conventional physiotherapy consists of using continuous ultrasound with a frequency of 3 MHz for 6 minutes around the shoulder joint capsule (20), high frequency transcutaneous electrical nerve stimulation (high-TENS; 80 Hz, 50 µs) with a time duration of 20 minutes (21), and the use of hot pack simultaneously with the application of the electrical current. For the involved shoulder, postero-anterior, anteroposterior, and caudal glides will be used at the rate of 2 to 3 glides per second and which continued for 30 seconds at each set (4). The number of sets for each glide is 5, and the rest interval between sets will be 30 seconds (4). To perform antro-posterior gliding techniques, the participant will be asked to lie in a supine position with the involved arm flexed about 90 degrees. After positioning, the therapist will perform antro-posterior and postro-anterior gliding techniques (22). For performing the caudal glide technique, the participant will be asked to lie in a supine position with the involved arm abducted about 90 degrees (22).

Besides, the participant will be asked to stretch the subscapularis muscle as well at the same time; they stand in a door frame with the GH joint in the middle position and stretch the subscapularis with the external rotation motion. During this stretch, the individuals can activate the subscapularis muscle by softly applying pressure (a minimal contraction) to the door frame (internal rotation) and holding it for 5-10 seconds. After relaxing the muscle, they stretch the muscle more by rotating themselves away from the affected side (15). Stretch maneuver can be performed three–five times and repeated up to 3-4 times daily.

Participants will also be asked to perform active-assistive exercises using a towel for 5 minutes daily (4). For this, they raise the hand of the un-involved above the head with an elbow flexed and laterally rotate the shoulder and grip one head of towel. The involved side will go back of the body internally rotated and grab the other head of the towel. With the help of the hand of the un-involved side, the involved side will be pulled upward (23).

Pulley exercises will be used to improve flexion and extension movements of the involved shoulder. The participant will be informed to sit on a chair holding a skipping rope that has passed over a pulley. Participants swing the rope alternatively up and down with the force generated by their un-involved side.

They will also be taught to perform Codman exercises in such a way that they will bend forward with a non-affected forearm supported on a table or couch, shoulder relaxed, and then gently swing the affected side arm forwards and backwards, side to side, clockwise and counterclockwise in pain-free range (24).

Finally, the participants will be instructed to exercise with a finger ladder to increase flexion ROM (table II).

Intervention group

Participants in this group will receive the exact treatment protocol of the control group, added 3 sessions of DN in the 3rd, 6th, and 9th sessions of the treatment. To do so, the MTrP will be determined and marked with a marker to remain constant during the treatment and study. The exact place of the subscapularis muscle MTrP should be sterilized using sanitary cotton and alcohol. For performing the DN technique, based on Dommerholt and Fernandez de-las-Penas approaches, participants will be asked to sit in a supine position on the bed, abduct the shoulder about 90 degrees, and externally rotate as much as possible. Bringing the scapula to the lateral side can make it easier to access the muscle. After determining and lifting the latissimus-dorsi tendon with a pincer grip, the
needle (Dong bang Acuprime Ltd, with dimensions: 25 mm × 50 mm, Korea) is inserted parallel to the chest and perpendicular to the anterior surface of the scapula to the MTrP (17). The exact place of MTrP must be confirmed with LTR. To release MTrP, the fast in-fast out technique will be performed, according to the recommendation of Hong (25). If LTR isn’t felt after moving the needle 10 times, we can stop the technique. If there is more than one MTrP, the most painful point will be detected and treated (figure 2).

Table II. Therapeutic interventions for participants in the present study.

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Duration</th>
<th>Dose/ frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antero-posterior glide</td>
<td>2-3 Hz for (30 seconds) × 5 sets</td>
<td>Once a day</td>
</tr>
<tr>
<td>Postero-anterior glide</td>
<td>2-3 Hz for (30 seconds) × 5 sets</td>
<td>Once a day</td>
</tr>
<tr>
<td>Caudal glide</td>
<td>2-3 Hz for (30 seconds) × 5 sets</td>
<td>Once a day</td>
</tr>
<tr>
<td>Active-assistive interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stretch the Subscapularis muscle</td>
<td>5-10 second × 3-5 times</td>
<td>3-4 times per day</td>
</tr>
<tr>
<td>Towel exercises</td>
<td>5 minutes</td>
<td>Once a day</td>
</tr>
<tr>
<td>Pulley exercises</td>
<td>5 minutes</td>
<td>Once a day</td>
</tr>
<tr>
<td>Codman exercises</td>
<td>5 minutes</td>
<td>Once a day</td>
</tr>
<tr>
<td>Finger ladder exercises</td>
<td>5 minutes</td>
<td>Once a day</td>
</tr>
<tr>
<td>Modalities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High frequency TENS</td>
<td>20 minutes</td>
<td>80 Hz, 50 μs</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>6 minutes</td>
<td>3 MHz</td>
</tr>
</tbody>
</table>

μs: Microsecond; MHZ: Mega hertz; TENS: Transcutaneous electrical nerve stimulation; HZ: Hertz.

Figure 2. Study timeline according to the SPIRIT checklist recommendation.
T: Treatment session; ROM: Range of motion; VAS: Visual analogue scale; MTrP: Myofascial Trigger Point.
Choice of comparators
According to a reference (26), a combination of DN and conventional physiotherapy may have more positive effects than DN or conventional physiotherapy alone. Still, this hypothesis needs to be investigated in more musculoskeletal issues, including frozen shoulder.

Criteria for altering or stopping assigned treatments
If a participant would be absent for 2 successive sessions or wouldn’t be willing to complete the treatment procedure for any reason, the process would be dismissed and another eligible participant would be recruited.

Ways to enhance compliance with interventions
To motivate participants to complete their treatment procedure, all therapeutic intervention is free, and participants can be in contact with their therapist online or by phone to ask their clinical questions. Their personal information will be kept confidential and ensured that they won’t suffer any physical or emotional damage.

Relevant concomitant care permitted or prohibited during the trial
Participants will be allowed to consume analgesics like acetaminophen or ibuprofen if they can’t tolerate the pain caused by DN (27). In the case of using any special drug, they must consult with the doctor to prevent any drug interaction.

Sample size calculation
The sample size is determined with 3.1.2G power software with a power size of 0.8, α error probability of 0.05, and an effect size of 0.5 with a dropout probability of 20%. For two groups, 40 subjects (20 subjects for each group) are calculated. It should be noted that the effect size was determined according to Kalia’s study with the mean and standard deviation of the pain intensity variable (4).

Recruitment and sequence generation
The Participants will be people referred to the physiotherapy clinic by orthopedists or rheumatologists. All participants in the study will be divided randomly into MTrP-DN of the subscapularis muscle plus conventional physiotherapy (intervention group) or conventional physiotherapy alone (control group) with an allocation ratio of 1:1. Participants will be randomly assigned to either group A (intervention) or group B (control) using a random allocation software. Randomization will be conducted using permuted blocks of 4 and 8. Then, the randomization schedule will be written on a paper with sequential numbers, and the papers will be placed in a sealed envelope. Someone outside the research team will do this procedure before the initiation of the trial.

Mechanism of allocation concealment
Each participant will receive a sealed envelope based on their assigned number after the initial assessments. After including each participant, the therapist will decide how to perform the treatment based on the group they allocated. To avoid bias, participants will be acknowledged to not reveal their allocated group to the outcome assessor.

Conduction
An individual who is not part of the study will conduct the allocation sequence, enrollment, and assignment of individuals to study groups.

Blinding
This is a single-blind study, and the outcome assessor is going to be blinded to the allocation sequence by the time the trial is conducted.

Permissible instances for unblinding
It is unacceptable for the outcome assessor to become unblinded during the process. After completing the participants assessment, they can be un-blind and informed about groups.

Primary outcome
The primary outcomes for this study are pain intensity and ROM, which would be felt in the shoulder region.

Pain intensity
Pain intensity of the shoulder region and subscapularis MTrPs will be evaluated by VAS which is a reliable and valid scale for chronic and experimental pain (28). VAS is once assessed at baseline and once after completing treatment sessions. For each time, the assessment will be conducted thrice, and the average outcome will be communicated. Participants will be asked to mark the intensity they feel in the affected shoulder region from zero (no pain) to 10 (the most severe pain that could be imagined). To measure subscapularis MTrP pain intensity, for 3 seconds, the pressure of 2.5 kg/cm² at MTrP will be applied with a rate of 1 kg/cm².s⁻¹ by digital algometer) FDX 50 force Gage, Wagner Instruments, United States (while the subjects are marked their pain intensity on the VAS to determine local pain evoked by applying pressure on the MTrP.

Range of motion of glenohumeral joint
The assessor would determine the GH joint ROM of the participants using a goniometer at baseline, and after completing the treatment sessions. Assessments will be performed three times and the mean will be reported.
**Glenohumeral joint flexion**
Participants will be asked to lie in a supine position with hands beside the body in a neutral position. The center of the goniometer will be matched with the lateral aspect of the greater tuberosity, the proximal arm aligned with the midaxillary line of the thorax, and the distal arm with the lateral midline of the humerus. Participants are asked to raise their affected arm in the sagittal plane (29).

**Glenohumeral joint abduction**
The participants will be asked to lie down in a supine position with hands on the supination position. The center of the goniometer will be matched to the anterior aspect of the acromial process; the proximal arm of the goniometer should be aligned with the midline of the sternum, while the distal arm should be aligned with the anterior midline of the humerus. After that, the participants will be asked to raise their affected arm in the frontal plane (29).

**Glenohumeral joint internal/external rotation**
For measuring internal rotation, the participant will be asked to lie down in the supine position, with shoulder and elbow at 90 degrees of abduction and hand in the pronated position. A rolled towel is placed under the distal of the humerus to keep the humerus parallel to the ground. The center of the goniometer will be considered over the olecranon process, the proximal arm will be perpendicular to the floor, and the distal arm will be aligned with the ulna. The olecranon process and the ulnar styloid process are considered reference points. To measure internal rotation, the participant will be asked to close the palmar surface of the affected hand to the ground (29). For measuring external rotation, the participant will be asked to close his/her dorsal surface of the affected-side hand to the ground (29).

**Secondary outcome measures**
The secondary outcome measures of this study will be upper limb functional disability and PPT.

**Upper limb functional disability**
To assess upper limb functional disability, participants will complete the DASH questionnaire (Persian version) in the 1st, 5th, and 10th sessions of their treatment in the control and intervention groups. The DASH questionnaire (Persian version) is a valid and reliable questionnaire that contains 30 items about the difficulty of performing daily routine tasks to evaluate the upper limb dysfunctions during performing the tasks (30). Higher DASH scores represent more severe functional disability of the upper limb. The participants can ignore 3 items during answering. Computing will be performed with formula beyond: 
\[
\frac{(\text{sum of } n \text{ responses})}{n} 
\times 1 \times 25
\]
where \( n \) denotes the number of completed items (22).

**Pain pressure threshold**
PPT of subscapularis muscle MTrP will be assessed by an Algometer) FDX 50 force Gage, Wagner Instruments, United States, at baseline and the end of the treatment sessions. To measure PPT, the participants will be asked to lie in a supine position with 90 degrees of abduction, and elbow flexion with the dorsal of the hand on their forehead. The algometer will be placed on the subscapularis muscle MTrP, and the compression force applied by the assessor’s hand will gradually increase. The participant will be asked to report the moment when the pressure feeling turns into pain feeling. PPT will be assessed before initiation of treatment and after completing treatment sessions. For each time, PPT will be assessed three times with a resting interval time of 10 seconds, and the mean will be recorded.

**Adverse events**
Adverse events that may have occurred are classified into major and minor adverse events. Inserting a needle into the skin possibly causes complications like bruising, bleeding, post-dry needling soreness, and pain during or after performing the dry needling technique (13, 31, 32). If any adverse events that are shown in table III happen, it is the liability of the PT to report it.

**Strategies to encourage participants to stay involved and follow through with the program completion**
During the procedure period, the participants will be encouraged to be present regularly in the physiotherapy clinic by their PT. If they have any issues with how to perform their therapeutic exercises, they can ask PT in person or by phone. All treatment procedures would be free, and participants are not supposed to pay anything at different stages of the study.

**Table III. Potential adverse events.**

<table>
<thead>
<tr>
<th>Minor Adverse events</th>
<th>Major Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td>Pneumothorax</td>
</tr>
<tr>
<td>Bleeding</td>
<td>Excessive bleeding</td>
</tr>
<tr>
<td>Feeling faint</td>
<td>Syncopal responses</td>
</tr>
<tr>
<td>Headache</td>
<td>Infection</td>
</tr>
<tr>
<td>Nausea</td>
<td>Forgotten needle</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>Fainting</td>
</tr>
<tr>
<td>Aggravated symptoms</td>
<td>Numbness</td>
</tr>
<tr>
<td>Pain during and after intervention</td>
<td>Prolonged symptoms aggravation</td>
</tr>
<tr>
<td></td>
<td>Lower limb weakness</td>
</tr>
</tbody>
</table>

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Data management
The assessor will store participants’ personal information, pre-intervention, and post-intervention measures in a confidential Excel file for analysis.

Analyzing outcomes with statistical methods
SPSS software version 5 (SPSS Inc., Chicago, IL, USA) will be used. To compare the variables between the first and the tenth sessions, in the control and intervention groups and between the two groups, the Pair t-test and Independent t-test will be used respectively. In addition, a comparison of the changes in the severity of functional disability of the upper limb between the treatment sessions in both the intervention and control groups will be performed using Repeated Measures. The significance is set at p < 0.05. Shapiro-Wilk test will be used to evaluate the normal distribution of data, and if the distribution of measured data is expected, the parametric tests will be used. Additional analysis of results (e.g., subgroup analyses) is not predicted to be conducted.

Managing non-adherence and loss of follow-up data
Non-adhering or loss to follow-up data is going to be addressed using intention-to-treat analysis.

Monitoring the data collection
The trial will be supervised by faculty members of the Physiotherapy Department of Tabriz University of Medical Sciences. Interim analysis and auditing are not predicted in this trial.

Harms and medical care after potential harm
All participants will be informed about possible harms that may occur during MTrP-DN of the subscapularis muscle before they participate in the study. Possible harms will be handled by an expert PT, and the research team is liable for reporting any adverse events of the trial. The research team is responsible for compensating for any adverse events of MTrP-DN or any harm during the study.

Protocol amendments
If there were any amendments in the protocol, new changes will be uploaded to the registration organization website.

Consent or agreement and confidentiality
The informed consent form is prepared by the standards of the Ethics Committee of Tabriz University of Medical Sciences. The form is going to be collected by the clinic’s secretary from the participants. All eligible participants will receive information about the possible benefits and potential harms before signing the informed consent form. Any personal information from the participants will be stored confidentially during the trial timeline and also will be kept confidential after completing the treatment procedure.

DISCUSSION
“Frozen shoulder” which causes burning and throbbing pain sensation in the shoulder region and severe loss of motion, is one of the most common conditions encountered by orthopedic surgeons (5, 18). Different treatments have been introduced for this condition, which is usually accompanied by side effects. Alongside, physiotherapy is considered one of the effective methods in the treatment of frozen shoulder (15). Although the frozen shoulder is recognized as a capsular problem, the presence of MTrPs in the rotator cuff muscles may induce or exacerbate this condition, so it seems that releasing them may have positive effects on improving muscle activity and increasing ROM (4, 18, 19, 31, 33, 34). Among these muscles, the subscapularis muscle is one of the most common muscles prone to developing MTrPs, which causes restriction of abduction and lateral rotation of the GH joint (11). In contrast, lateral rotation is a prerequisite for complete elevation (abduction and flexion) of the humerus (11). Moreover, it is not possible to fully supinate the outstretched upper limb because of restricted lateral rotation of the shoulder. Thus, the subscapularis muscle MTrPs can impair shoulder and hand function (11).

DN, as a new intervention in the field of physiotherapy, has been shown to have a positive effect on increasing the ROM and reduction of pain in people with chronic shoulder pain (35-37). DN with vasodilation in small vessels may improve blood circulation and oxygen levels (38-40). With LTR, DN may regulate spontaneous electrical activity levels in active MTrPs and may suppress substance P and calcitonin-generated peptide levels in active MTrPs (41). Furthermore, DN may influence the peripheral sensitization and pain processing centers in the central nervous system by releasing peripheral opioid analgesia (42) and indirectly activating dorsolateral tracts, respectively (12).
There is limited evidence for DN as an effective method in people with frozen shoulder (4, 43). Our study is the first study which is designed to evaluate the impact of DN in people with frozen shoulder. We expect that MTrP-DN of the subscapularis muscle plus conventional physiotherapy will have a more positive effect on frozen shoulder clinical symptoms compared to conventional physiotherapy alone (26), and DN could be considered as a complementary treatment in these people.

Limitations of this study are lack of follow-up and ignoring releasing possible MTrPs that could exist in other muscles in the shoulder region due to the interactions among muscles affecting the results of our study. Therefore, designing new studies with the approach of investigating the effect of dry needling on other muscles is suggested. Also, applying the sham dry needling technique for the control group is recommended in future studies. Furthermore, post-needling soreness, a frequent event after dry needling, should be considered as a factor that may have an effect on pain intensity and sensitivity. So, the assessment of post-needling soreness needs to be taken into account in future research.

CONCLUSIONS

In summary, this study is designed to investigate the impact of MTrP-DN of subscapularis muscle to conventional physiotherapy in patients with frozen shoulder. The final results may enhance the body of evidence of adding DN as a therapeutic intervention to conventional physiotherapy to improve clinical symptoms of various musculoskeletal disorders including frozen shoulder.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

AM: conceptualization, methodology, writing - original draft. HA: conceptualization, methodology, supervision, writing - original draft, writing - review & editing. JA, AEO: writing - review & editing, project administration.

ACKNOWLEDGMENTS

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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