Research Paper

Iliopsoas Dry Needling for Non-specific Low Back Pain: Protocol for a Randomized Controlled Trial

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ABSTRACT

Purpose: Non-specific chronic low back pain (CLBP) is a prevalent musculoskeletal dysfunction. The development of myofascial trigger points (MTrPs) in the lumbopelvic muscles can exacerbate the symptoms in patients with CLBP, and the release of the iliopsoas muscle is often overlooked by clinicians. Dry needling (DN) may be beneficial for the release of MTrPs. Due to the scarcity of evidence on this issue, this study protocol aims to examine the impact of iliopsoas DN on pain severity and clinical symptoms in patients with CLBP.

Methods: A single-blinded randomized controlled trial will be conducted, including 40 patients with CLBP aged 35-60 years, assigned to control and intervention groups in a 1:1 ratio. Both groups will receive 10 sessions of conventional physiotherapy, with the intervention group also receiving iliopsoas DN. The primary hypothesis is that the treatment provided to the intervention group will lead to a more significant improvement in pain intensity than in the control group. The primary outcomes are low back pain intensity and pain intensity of the MTrP in the iliopsoas muscle. Secondary outcome measures will be pain pressure threshold (PPT0, functional disability, and anxiety and depression scale. Data will be collected at baseline and after the completion of the treatment procedure.

Results: Data analysis will compare baseline and post-treatment measures between the two groups. Statistical comparisons are expected to reveal a greater decrease in both general low back pain intensity and pain intensity of the MTrP in the iliopsoas muscle in the intervention group. Furthermore, we anticipate a significant difference between the groups in terms of increased pain pressure threshold, improved functional ability, and reduced psychological distress, favoring the combined therapy.

Conclusion: To help improve decisions about managing symptoms related to CLBP, this study will evaluate the effects of iliopsoas DN and physiotherapy, compared with physiotherapy alone, on symptoms in patients with CLBP. DN could be presented as an adjunct treatment for such patients, provided that the deactivation of MTrPs in the iliopsoas muscle using DN would have a beneficial impact.

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Highlights

● This study protocol elaborates on the importance of LBP as the primary musculoskeletal condition and the role of developing MTrP in these patients, along with the biomechanical role of the iliopsoas muscle, often referred to as the "forgotten muscle," in these patients.

● If clinical features show improvement, DN of the iliopsoas MTrP could be introduced as a complementary treatment alongside conventional physiotherapy for patients with chronic low back pain.

Plain Language Summary

The development of low back pain (LBP) is one of the most prevalent causes of disability. However, without addressing the origin of the pathology or the level of disability, the development of myofascial trigger points (MTrP) in the lumbopelvic muscles is inevitable whose presence may exacerbate the symptoms in these patients; clinicians often overlook the release of the iliopsoas MTrP, while dry needling (DN) is one of the new and rapid treatments in the field of muscle release and, if effective, can be considered as a complementary treatment alongside other treatments for these patients.

Introduction

Low back pain (LBP) is a disabling, common condition affecting a substantial portion of the population [1]. The prevalence of LBP is estimated to be 30-80% [2]. LBP refers to pain, stiffness, or discomfort in the lower back from the lower ribs to the top of the gluteal fold [3]. Since LBP, especially in the chronic phase referred to as chronic LBP (CLBP), is a multifactorial phenomenon, there are several approaches to its treatment.

Given the potential musculoskeletal origin, an imbalance between the trunk and hip muscles is identified as an important factor in the occurrence of CLBP [4-6]. The iliopsoas muscle is the major compressor of the lumbar spine, and its overactivity could hinder the spinal vertebra's health [7-9]. In contrast, the iliopsoas muscle is crucial for pelvic mobility and stability. The short length of the iliopsoas could lead to spine hyper-lordosis, anterior pelvis tilt, and increased stress on the erector spinae [10, 11]. These changes may initiate or aggravate symptoms of patients with CLBP. In the event of overuse or injury, the iliopsoas muscle can develop myofascial trigger points (MTrPs). MTrPs are hyper-irritable points in the taut band of skeletal muscle or fascia causing referred pain and local sensitivity [12]. Iliopsoas MTrP referral pain usually presents as non-radicular pain that extends vertically along the lumbar spine and sacroiliac region [12].

Lack of physical activity and prolonged poor posture may be possible causes of MTrP development in the myofascial system [13-15]. Based on a study, up to 90% of patients with CLBP develop myofascial dysfunction in the lumbosacral area, and 31% of this population develop MTrP in the iliopsoas muscle [16]. Indeed, the iliopsoas muscle is one of the main lumbar muscles affected by MTrP in these patients [16]. Despite the frequent occurrence of MTrPs in the iliopsoas muscle, addressing them in this muscle is frequently neglected in the treatment of CLBP. This oversight is primarily due to challenges in palpating and visually inspecting the muscle given its deep location, as well as the nonspecific and variable symptoms of its MTrP, which often overlap with other issues. Also, functional disorders of this muscle are a neglected source of pain [17].

The conventional physiotherapy program alleviates the CLBP symptoms [16]. Dry needling (DN) is a new and effective method for myofascial problems [17, 18]. Myofascial trigger point dry needling (MTrP-DN) is defined as the insertion of a solid filament needle into the muscular MTrP to improve or restore muscle function following a local twitch response (LTR) [19].

Evidence is scarce regarding the impact of iliopsoas MTrP-DN in patients with CLBP [20, 21]. In one study, the effects of the iliopsoas MTrP-DN and therapeutic stretching were evaluated in six patients with ipsilateral foot drop and acute sciatic pain. The results revealed that iliopsoas muscle release is a reasonable therapeutic option, and DN may have greater benefits than conservative physiotherapy in these patients. However, the evi-

dence may support the use of the iliopsoas MTrP-DN to improve LBP; however, due to the study's small sample size and its inclusion of only patients with acute sciatica, the results cannot be generalized to other patients with LBP. Therefore, it seems necessary to design studies with larger sample sizes and different etiologies in patients with LBP [21]. Furthermore, another study suggests that DN of lumbopelvic muscles can be an efficient treatment for patients with CLBP; however, it did not consider releasing the iliopsoas muscle MTrPs [20].

Given findings from previous studies, DN is often applied to muscles in the lumbopelvic area, while the importance of releasing the iliopsoas muscle is mostly neglected or overlooked as a complement to conventional physiotherapy programs in patients with CLBP [22, 23]. Therefore, this single-blinded randomized controlled trial is designed to examine the effect of iliopsoas MTrP-DN and physiotherapy, compared to physiotherapy alone, in patients with CLBP.

The study hypothesizes that patients receiving MTrP-DN alongside a conventional physiotherapy program will show greater improvement in LBP symptoms, such as pain intensity in the lumbar and MTrP (as primary outcomes), anxiety and depression levels, pain pressure threshold (PPT) at the iliopsoas muscle MTrP, and functional disability (as secondary outcomes) compared to those receiving only conventional physiotherapy.

Materials and Methods

Study design

This study will be a monocenter, superior, randomized, single-blinded, controlled trial with parallel groups of 40 patients, with the outcome assessor blinded to the interventions. The allocation ratio will be 1:1. This study follows the standard protocol items: recommendations for interventional trials (SPIRIT) guidelines. This study has been registered at the Iranian Registry of Clinical Trials (IRCT), registered on 2023-09-24.

Informed consent

The study will be conducted in accordance with the Declaration of Helsinki. Participants will be informed in detail about the trial goal, interventions, benefits, and possible side effects. They can withdraw from the study at any stage. Before recruitment, the physiotherapist responsible for assessing the patients will collect written informed consent. This study has been approved by the Research Ethics Committee of Tabriz University of Medical Sciences on 2023-09-04.

Participants

Eligible subjects with CLBP will be recruited from the physiotherapy clinics at Tabriz University of Medical Sciences in this study. Participants will be evaluated with the inclusion and exclusion criteria before entering the trial. The inclusion criteria include age 35-60 [23], duration of CLBP of at least 3 months, disability level with Quebec back pain disability scale (QBPDS) more than 40, and presence of MTrP in the iliopsoas muscle. The exclusion criteria include the coincidence of the trial with any physiotherapy intervention, sensory or cognitive disorder, specific LBP (i.e. spinal canal stenosis, spondylolisthesis, and tumor), needle phobia, epilepsy, pregnancy, and history of spine surgery.

Procedure

The target population of the trial will be patients with CLBP who are referred to the clinic. The trial will be performed in a physiotherapy clinic under the supervision of the Tabriz University of Medical Sciences, Rehabilitation Faculty. After completing informed consent, 40 patients will be randomly allocated into the intervention and control groups. The control group will receive 10 sessions of a conventional physiotherapy program, including ultrasound, transcutaneous electrical nerve stimulation (TENS), and exercise therapy, and the intervention group will receive a conventional physiotherapy program plus 6 sessions of the iliopsoas MTrP-DN technique. An experienced physiotherapist will assess the patients once at the baseline and once after completing the last treatment session. Demographic information and study-related data will be coded and stored confidentially in numerical order. A double-review strategy will be adopted to minimize errors, ensure accurate data entry, and identify missing items. Figure 1 shows a CONSORT flow diagram related to the stages of the protocol.

Randomization and blinding

Patients will be randomly assigned to control (A) or intervention (B) groups using a randomizer site. Someone outside the study will do the randomization process with a 1:1 allocation. The randomization process will be conducted with three blocks of 4, two blocks of 8, and two blocks of 6 arranged in a random sequence. After allocating each participant to the study, their group names will be deleted from the block. This process results in an equal number of ''control groups'' and '' intervention groups.'' After deleting all group names from a specific block, the block will be blank, and the group names will be located in the sealed envelope. A person not involved

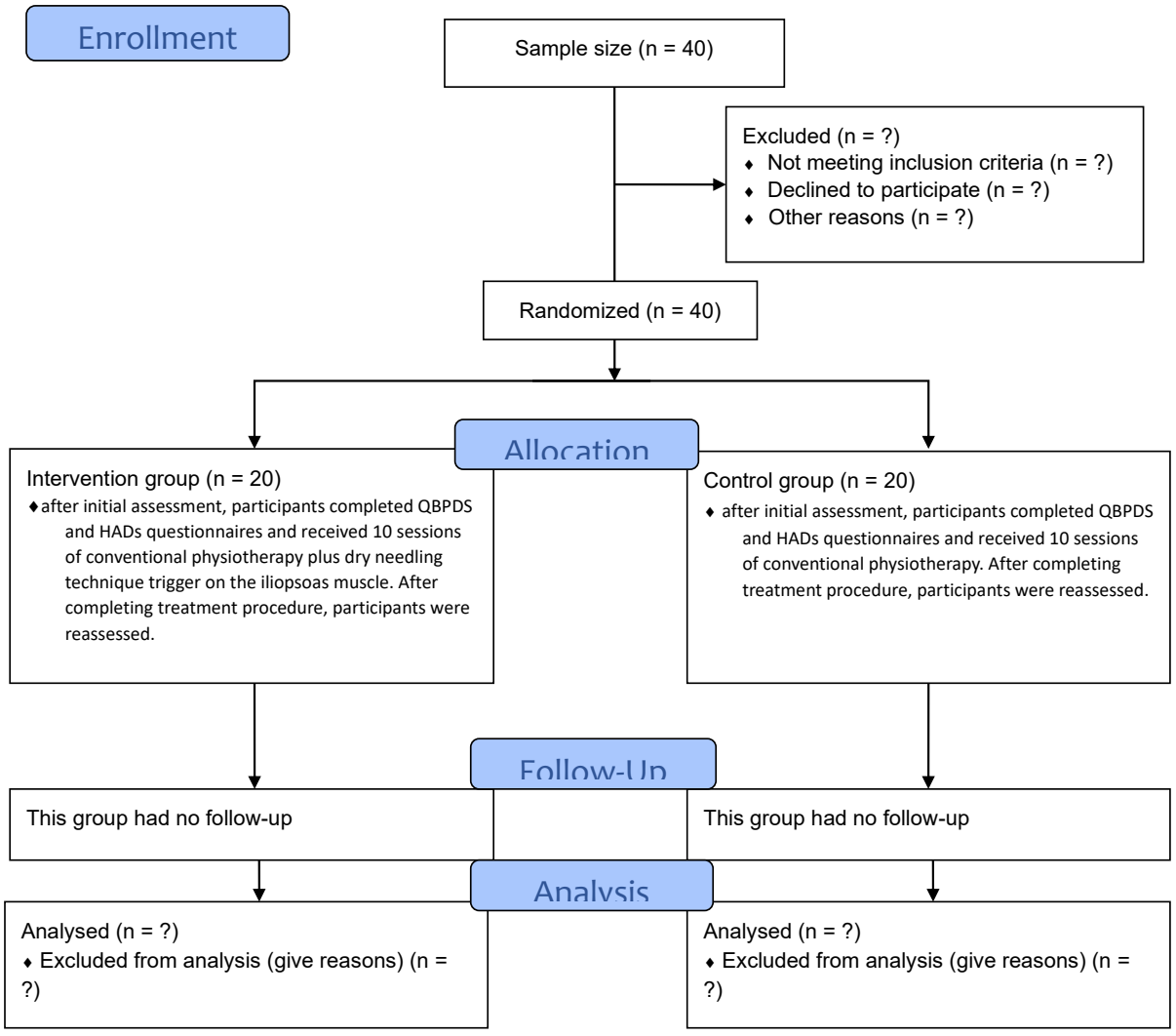

Figure 1. CONSORT flow diagram of the current study

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in the study was responsible for managing the envelopes for allocation concealment. After that, the next block will be opened according to its sequence. Participants are allocated to groups and their confidentiality is preserved by the secretary of the physiotherapy clinic after the initial assessment. The outcome assessor will not be informed about the number of blocks and the sequence in which they are arranged.

Sample size

Using G*Power software, version 3.1.9.2 the following parameters are determined: α error probability of 0.05, effect size of 0.5, power of 0.8, 20% dropout probability for two groups, and a sample size of 40 (20 people in each group). The effect size, Mean±SD for pain intensity will be determined according to the study by Álvarez et al. [24].

Diagnosis ofMTrP

The precise location of the active iliopsoas muscle MTrPs will be determined by a professional physical therapist considering the Travell and Simons' criteria [12]: A hypersensitive tender spot in the taut band, presence of a taut band within the muscle, LTR on snapping palpation, spontaneous pain, and a familiar referred pain on palpation. Patients will be asked to lie supine with the slightly affected side hip in abduction. MTrPs can be identified with a cross-fiber flat palpation of the psoas musculotendinous junction and the iliacus muscle fibers against the lateral wall of the femoral triangle. If the iliacus muscle is short, it is important to semi-flex the hip by placing a foam roll under the thigh. To locate the common iliopsoas tendon, the assessor should palpate the femoral artery in the femoral triangle. Then, to reach the tendon, the palpating finger will be swept about one

to two fingers palm laterally over the femoral nerve. To confirm that the clinician is palpating the iliopsoas tendon, the patient will gently contract the muscle by lifting the leg [25]. The presence of MTrPs in the iliopsoas muscle will be diagnosed in both groups.

Interventions

Control group

The participants in the control group will undergo a conventional physiotherapy program. The conventional program includes applying TENS in burst mode with a pulse width of 100 μs, a duration of 20 minutes, and a frequency of 2 Hz [20], while a hot-pack is used with TENS simultaneously. Ultrasound, continuous mode, with a frequency of 1MHz, with a duration of 6 minutes and intensity of 1.5 W/cm^2 will be applied at the lateral side of the lumbar spine ipsilaterally [20]. An expert physiotherapist will perform all the therapeutic actions in the study groups. The patient will be asked to do exercises. Table 1 presents the set of recommended exercises for participants. The recommended exercises for participants in the present study are as follows:

Isolated contraction of the transverse abdominis: For this exercise, patients will be asked to flex the knees with the pelvis in a neutral position and then imagine that they are trying to put on tight jeans.

Pelvic elevation with transverse abdominis contraction: This exercise is similar to the previous one, except that after completing the task, patients will be asked to raise their pelvis.

Lift one foot 2 cm while the pelvis is elevated: This exercise is more complicated than pelvic elevation with transverse abdominis contraction. Once the pelvic elevation is performed, we will ask the patients to lift one foot approximately 2 cm from the ground.

Co-contraction of multifidus and transverse abdominis: Patients will be asked to lie prone, with feet on the pillow and knees flexed. Afterward, they will be asked to contract the transverse abdominis as in the first exercise and slowly contract the multifidus.

Head and shoulder lift on the elbow: Patients will be asked to flex their knees with the pelvis in a neutral position, then lift their shoulders and head, holding that position for 5 seconds.

Seating on a chair: Keeping the feet on the floor with knees aligned with the hip. The weight will be applied to both the ischial tuberosities and the spine in a neutral position.

Piriformis stretch: Patients will be asked to place the lateral side of the foot on the contralateral knee and pull the knee toward the chest.

Erector spine stretch: Patients will be asked to sit on their knees, flex the trunk, and stretch the arms forward.

Intervention group

The patients in the intervention group will benefit from the conventional physiotherapy program. They also received six sessions of iliopsoas DN on the first, third, fifth, seventh, ninth, and tenth days, concurrently with their con-

Table 1. The set of the recommended exercises for participants of the present study in intervention and control groups

Exercise	Set
Isolated contraction of the transverse abdominis	10 contractions of 10 seconds
Pelvic elevation with transverse abdominis contraction	10 repetitions with 5 seconds hold
Lift one foot 2cm while the pelvic is elevated	10 repetitions
Co-contraction of multifidus and transverse abdominis	10 contractions of 10 10-second
Head and shoulder lift on the elbow	10 repetitions, lift and hold for 5 second
Seating on a chair	As much as possible
Piriformis stretch	Twice a day, 3 repetitions each time (30 seconds for each stretch with 20 seconds rest between)
Erector spine stretch	Twice a day, 3 repetitions each time (30 seconds for each stretch with 20 seconds rest between)
Aerobic exercise	20 to 30 minutes' walk with proper speed

ventional physiotherapy program [20]. To perform the DN technique, patients will be asked to lie supine on a bed and slightly abduct the affected hip. The MTrPs of the iliopsoas muscle are located at the intersection of the psoas and iliacus fibers with the lateral aspect of the femoral triangle. If the iliacus muscle is short, the hip joint is placed in a semi-flexed position by placing a foam roller below it. To palpate the iliopsoas joint tendon, the femoral artery, located in the femoral triangle, is first palpated and identified. Then, by moving the palpating finger two knuckles apart and asking the patient to slightly flex the hip joint, the iliopsoas tendon is palpated [25]. Initially, the MTrP site is cleaned using alcohol and a sterile cotton pad, and then a dry needle is inserted perpendicular to the MTrP (Dong Bang Acuprime Ltd., Korea; dimensions: 60×0.25 mm). For DN, the "fast-in fast-out" technique will be used, and for this purpose, the needle will be advanced and manipulated in the target area. The precise location of MTrP is determined by palpable or visible LTR. This technique is stopped when no further LTR is elicited, and the needle will be removed from the tissue. The MTrP location will be marked using waterproof ink to remain fixed throughout the treatment process [21].

Outcome measurement

Assessments

All participant variables in the control and treatment groups will be assessed at baseline and after completing the study procedure. The MTrP diagnosis and assessments will be performed by a professional physiotherapist with 15 years of experience in diagnosing and treating MTrP and musculoskeletal dysfunctions. Figure 2 shows the SPIRIT study timeline for study's stages.

Primary outcome measures

LBP intensity

The intensity of LBP will be assessed using the NPRS at baseline and after completing the treatment. NPRS has appeared reliable in assessing LBP severity [26]. The NPRS is an 11-point scale ranging from 0 to 10. Zero represents no pain, and 10 represents the worst pain ever experienced. The patients will be asked to report their current worst pain score during the day.

Pain intensity at MTrP of the iliopsoas muscle

Alongside back pain intensity, pain intensity at the MTrP of the iliopsoas muscle will also be measured. To measure this variable, a constant pressure of 2.5 kg/cm^2 was applied to the MTrP with a digital algometer (FDX 50 force Gauge, Wagner Instruments, USA) and maintained for 3 seconds. Subsequently, the patients will be asked to report the pain intensity they experienced using the NPRS scale.

Secondary outcome measures

Functional disability

The QBPDS will be used to measure the level of functional disability among people with LBP [27]. In this study, the Persian version of the QBPDS was used. The questionnaire has shown excellent test re-test reliability (intra-class correlation coefficient (ICC): 0.86) and validity in patients with CLBP [28]. The scale has one main form for questioning: "Do you have problems with ... today?" This questionnaire has 20 questions about routine daily tasks, such as getting out of bed, and taking something out of the refrigerator. Participants rated each question on a scale from 0 (no effort) to 5 (unable to do). A higher score indicates greater disability [28, 29].

Anxiety and depression

There is a close and mutual relationship between the occurrence of CLBP and the alteration of normal psychological situations to anxiety and depression [30]. The occurrence of depression and anxiety among patients with chronic musculoskeletal pain is high, influencing the efficiency of rehabilitation programs [31]. Hospital anxiety and depression scale (HADS) is a suitable screening tool for assessing these variables in clinical practice [32]. This questionnaire has seven questions for anxiety and seven questions for depression. The answer to each question is scored from 0 to 3. A higher HADS score indicates the severity of depression and anxiety. The Persian version of HADS, a reliable and validated tool, will be used for assessing depression and anxiety in this study [33]. Anxiety and depression are measured with separate questionnaires, and each one scores 0-21.

PPT

The PPT will be evaluated using a digital algometer (FDX 50 force gauge, Wagner Instruments, USA). The algometer is placed vertically on the MTrP of the iliopsoas muscle. Then, the pressure will be increased at a constant rate, and the participant is asked to report the exact time at which the feeling of pressure changed into pain, and the amount of pressure was recorded [34]. The PPT will be measured three times, with a resting interval of ten seconds, according to the report [35].

	STUDY PERIOD											
	Enrolment	Allocation	Post-allocation									
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}
ENROLMENT:												
Eligibility screen	X											
Informed consent	X											
[List other procedures]	X											
Allocation		X										
INTERVENTIONS:												
Study groups												
Intervention group			X		X		X		X		X	X
Control group												
ASSESSMENTS:												
Back pain intensity		X										X
Pain intensity at MTrP		X										X
Functional disability		X										X
Pain intensity *at MTrP*		X										X
Pain pressure threshold		X										X
anxiety and depression		X										X

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Figure 2. Study timeline according to the SPIRIT checklist recommendation

Abbreviations: SPIRIT: Standard protocol items: Recommendations for interventional trials; -t1: Pre-study: screening; t0: Pre-study: Randomization; t1-t10: Treatment sessions from session 1 to session 10; MTrP: Myofascial trigger point.

Data monitoring and availability

An independent physical therapist will monitor the methodology to ensure adherence to the proposed methodology and accurate data collection. It is worth mentioning that after completing the recruitment procedure, the raw data will be available upon request to the corresponding author.

Data analysis

The SPSS software, version 25 (SPSS Inc., Chicago, IL, USA) will be used. Shapiro-Wilk (S-W) test will be used to detect the normal distribution of data. The independent t-test and paired t-test will be used to compare variables between the first and the tenth sessions, within the control and intervention groups, and between the two groups. Statistical significance is set at $P<0.05$. If any differences arise between the groups based on baseline factors, such as age and initial pain intensity, we will include subgroup analysis to improve our understanding of treatment efficacy and offer more detailed insights into our findings.

Results

This study will present the effects of iliopsoas DN and physiotherapy, compared with physiotherapy alone, on pain intensity in the lumbar region, MTrP, PPT of the iliopsoas muscle, functional disability, and anxiety and depression scores.

Discussion

CLBP is a complex issue that can have various origins, such as muscle malfunction in the lumbar region [35]. The iliopsoas muscle is a crucial muscle involved in

many daily activities [9], and its normal function needs extra consideration. The development of MTrP in lumbopelvic muscles, especially the iliopsoas muscles, is prevalent in patients with CLBP, which could be a certain cause for aggravating the symptoms of the patients [9].

The inflexibility of the iliopsoas muscle due to its attachment to the lumbar vertebra leads to excessive compressive and shear forces on the spine, and restoration of its length is necessary [9]. Several studies have reported the effectiveness of iliopsoas muscle release using the muscle energy technique (MET), stretching, and proprioceptive neuromuscular facilitation in improving range of motion and other symptoms in patients with LBP [10, 11]. DN is a novel technique for the treatment of MTrP and could lead to the rapid elimination of pain, reduced muscle stiffness, and muscle elongation [18, 19]. In comparing the effectiveness of DN and MET in the release of the quadratus lumborum muscle, it has also been reported that DN is more efficient in improving the symptoms in patients with LBP compared to MET [36]. It seems that incessant input to the muscles afflicted by MTrP could lead to neuro-plastic alterations in the dorsal horn of the spinal cord, and that proper interference should have both central and peripheral effects [37, 38].

Plausible mechanisms of DN to deactivate the MTrP are grounded on mechanical, neurophysiological, and biochemical effects. For analgesic effects of DN, it is reported that when A-delta fibers are stimulated via the needle, the release of enkephalins in the posterior horn of the spinal cord is increased [38]. Also, this may induce the descending pain-inhibitory system. On the other hand, induction of the LTR in DN may have mechanical effects. Indeed, LTR leads to localized stretch to the contractured cytoskeletal structures and, as a result, causes a mechanical disruption of MTrP in the muscle [39]. Furthermore, based on previous studies, biochemical substances in active MTrPs differ from those in normal muscle sites [40]. Alterations in intramuscular blood circulation and decreased levels of chemical substances, such as substance P and calcitonin-generated peptide, in the MTrP region could be due to biochemical changes following dry needling and may explain the therapeutic effects of DN on pain alleviation in the MTrP region [41].

Although the positive effect of MTrP-DN on the different muscles of patients with LBP was asserted [19, 20, 24, 42], evidence for applying DN to the MTrP of the iliopsoas muscle is scarce [19-21]. Consequently, this study aimed to determine the impact of the MTrP-DN on the iliopsoas muscle and provide useful information to help make better decisions about managing symptoms related to CLBP. If the combination of conventional physiotherapy and DN technique produces more positive effects than physiotherapy alone, this protocol could be presented as a beneficial treatment that improves the functional ability and the quality of life of patients with CLBP.

This study has some limitations. First, although the researchers investigated the direct effect of MTrP-DN on the iliopsoas in patients with CLBP, the presence of MTrPs in other muscles, such as the multifidus, the gluteus medius, and the quadratus lumborum, may mimic the symptoms and affect the results. Designing future studies with appropriate inclusion criteria (excluding MTrPs in other lumbopelvic muscles) may be a control strategy to eliminate this limitation. Second, while the treatment program for CLBP may require attention to psychosocial or behavioral therapy, only the musculoskeletal origin is targeted. Designing a multifactorial treatment that considers these perceptions is suggested for future studies. Additionally, because of the invasive nature of the DN technique, preparing the setting for participant or DN performer building is challenging. It is assumed that including sham-DN treatment with a toothpick Steinberger needle in the control group could help assess the placebo effect of releasing the muscle with DN.

Table 2. Possible adverse events of dry needling

Adverse events	
Minor	Pain during MTrP-DN performance Pain after MTrP-DN performance Bleeding Bruising Aggravated symptoms Nausea
Major	Excessive bleeding Infection Numbness Prolonged symptoms aggravation

MTrP-DN: Myofascial trigger point dry needling.

Adverse events

Although DN is considered a safe treatment, some adverse events have been reported. Table 2 presents possible adverse events. If any of these events occur, the physiotherapist in charge of the treatment is responsible for reporting them.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Research Ethics Committee of Tabriz University of Medical Sciences, Tabriz, Iran (Code: IR.TBZMED.REC.1402.424). this study was registered by the Iranian Registry of Clinical Trials (IRCT), Tehran, Iran (Code: IRCT20200215046499N4).

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Although this study was conducted under the supervision of the Rehabilitation Sciences Faculty at Tabriz University of Medical Sciences, the study team will not receive any funding from the university or any other organization for any stage of the study.

Authors' contributions

Conceptualization and Supervision: Hakimeh Adigozali, Zahra Salahzadeh; Methodology: Niloofar Roghangar, Amir Masood Arab, Amin Momenzadeh; Investigation, Writing the original draft, review & editing: All authors.

Conflict of interest

The authors declared no conflict of interest.

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