Title: Impact of Iliopsoas Muscle Dry Needling on Symptom Relief in Patients with Non-Specific Low Back Pain: Study Protocol for a Randomized Controlled Trial

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Abstract

Background: Non-specific chronic low back pain (CLBP) is a prevalent musculoskeletal dysfunction. The development of myofascial trigger points (MTrPs) in the lumbopelvic muscles could exacerbate the symptoms of patients with CLBP and releasing the iliopsoas muscle is often overlooked by clinicians. Dry needling (DN) could be beneficial in releasing the 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 to include 40 patients with CLBP aged 35-60 years who will be assigned into control and intervention groups, with ratio of 1:1. 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 compared to 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, functional disability, and anxiety and depression scale. Data will be collected at baseline and after the completion of the treatment procedure.

Results and conclusion: To help make better decisions about managing symptoms related to CLBP, this study will evaluate the effects of iliopsoas DN and physiotherapy compared with physiotherapy alone on the symptoms of 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 bear beneficial impact.

Keywords: Dry Needling, Iliopsoas muscle, Low Back Pain, Physical Therapy Modalities, Trigger Points.

Level of evidence: 2

Highlights

This study protocol elaborates on the importance of low back pain as the primary musculoskeletal condition and the role of developing myofascial trigger points (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, dry needling 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 is one of the most prevalent origins of disability. However, without addressing the origin of the pathology or the level of disability, the development of myofascial trigger points in the lumbopelvic muscles is inevitable whose presence may exacerbate the symptoms in these patients; The release of the iliopsoas myofascial trigger points is often overlooked by clinicians while dry needling 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 the LBP, especially in the chronic phase referred to as Chronic Low Back Pain (CLBP), known as a multifactorial phenomenon, there are several approaches to its treatment.

Considering the potential musculoskeletal origin, the imbalance of 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 it's over activity could hinder the spinal vertebras' health [7-9]. On the other hand, the iliopsoas muscle is crucial for pelvic mobility and stability. The short length of iliopsoas could lead to the spine hyper-lordosis, the anterior pelvis tilts, and increased stress on erector spinae [10, 11]. These changes may initiate or aggravate symptoms of patients with CLBP. In case of overuse or injury, the iliopsoas muscle could develop Myofascial Trigger Points (MTrPs). MTrPs are hyper-irritable points in the taut band of skeletal muscles or fascia causing referred pain and local sensitivity [12]. The iliopsoas MTrP referral pain could usually appear as a non-radicular pain that extends vertically, at the same side, along the lumbar spine and sacroiliac region [12].

Lack of physical activity and prolonged bad posture could be some possible causes of developing MTrP in myofascial system [13-15]. Based on a study, up to 90 percent of patients with CLBP develop myofascial dysfunction in their lumbosacral area and 31 percent of this population, develop MTrP in the iliopsoas muscle [16]. Indeed, the iliopsoas muscle is one of the main lumbar muscles aggrieved by MTrP in these patients [16]. Despite the frequent occurrence of MTrPs in the iliopsoas muscle, addressing them in this muscle is frequently neglected when treating CLBP. This oversight is primarily due to challenges associated with palpating and visually inspecting the muscle, given its deep location, as well as the nonspecific and variable symptoms associated with 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 seems to alleviate the CLBP symptoms [16]. Dry needling (DN) is a new and effective method concerning myofascial problems [17, 18]. Myofascial Trigger Points Dry Needling (MTrP-DN) is defined as the insertion of the solid

filament needle into the muscular MTrP to improve or restore muscle function after a response called local twitch response (LTR) [19].

Evidence is scarce on the impact of the iliopsoas MTrP-DN on patients with CLBP [20, 21]. In one study, the effects of the iliopsoas MTrP-DN and therapeutic stretching were evaluated on six patients with ipsilateral foot drop and acute sciatic pain. The results revealed that the release of iliopsoas muscle is a decent therapeutic option and DN could have more positive effects than conservative physiotherapy in these patients. However, the evidence may support the use of the iliopsoas MTrP-DN in improving the symptoms of LBP, as a result of the small sample size of the study and its inclusion of only patients with acute sciatica pain, the results are not generalized to other patients with LBP. Therefore, it seems necessary to design studies with larger sample sizes as well as different etiology in patients with LBP [21]. Furthermore, in another study, the results suggest that DN of lumbopelvic muscles can be an efficient treatment in patients with CLBP, however it did not consider releasing the iliopsoas muscle MTrPs [20].

Given the findings from previous studies, the usage of DN is often conducted on muscles in the lumbopelvic area while the importance of releasing the iliopsoas muscle is mostly neglected or overlooked as a companion to conventional physiotherapy programs in patients with CLBP [22,23]. Therefore, this single-blinded randomized controlled trial is designed to examine the effect of the iliopsoas MTrP-DN and physiotherapy in comparison to physiotherapy alone on 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 mono-center, superior, randomized, single-blinded with the outcome assessor blinded to the interventions, a controlled trial with parallel groups of 40 patients. 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 Iranian Registry of Clinical Trials (code: IRCT20200215046499N4 registered on 2023-09-24).

Informed consent

The study will be conducted in line with Helsinki Ethical Principles declaration. 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 aproved in Research Ethics Committee of … University of Medical Sciences with the registration number (IR.TBZMED.REC.1402.424) on 2023-09-04.

Participants

Eligible subjects with CLBP will be recruited from the physiotherapy clinics at University of Medical Sciences in this study. Participants will be evaluated with the inclusion and exclusion criteria before entering the trial. The inclusion criteria are age 35 to 60 [23], duration of CLBP at least 3 months, disability level with Quebec back pain disability scale more than 40, and presence of MTrP in iliopsoas muscle. The exclusion criteria will be 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, history of spine surgery.

Procedure

The target population of the trial will be the patients suffering from CLBP who are referred to the clinic. The trial will be performed in a physiotherapy clinic under the supervision of the Rehabilitation Faculty. After filling out an 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, 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 the data related to the study 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. A CONSORT flow diagram related to the stages of the protocol is presented in Figure 1.

Randomization and blinding

Patients will be randomly assigned to a control group (A) or intervention group (B) with a randomizer site. Someone outside the study will do the randomization process with 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 name will be deleted from the block. This process will give us 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 sequence in the sealed envelope. A person not involved the study is responsible for managing the envelopes for allocation concealment. After that, the next block will be opened according to its sequence. Allocating participants to groups will be done and preserved confidentially by the secretary of the physiotherapy clinic after the initial assessment and the outcome assessor will not be informed about the number of the blocks, and the sequence in which they are arranged.

Sample size

Using 3.1.9.2G power software, the following parameters: α error probability of 0.05, the effect size of 0.5, power size of 0.8 with 20% dropout probability for two groups, and the number of 40 people (20 people in each group) will be determined. The effect size, mean, and standard deviation of the pain intensity variable will be determined according to the Álvarez study [24].

Diagnosis of MTrP

The precise locality of the active iliopsoas muscle MTrPs will be determined by a professional physical therapist considering the Travell and Simons' criteria [12]: (a) a hypersensitive tender spot in the taut band, (b) presence of a taut band within the muscle, (c) LTR on snapping palpation, (d) spontaneous pain, and (e) a familiar referred pain on palpation. Patients will be inquired to lie in a supine position with a 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 putting 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 the MTrP in the iliopsoas muscle will be diagnosed in both groups.

Interventions

Control group

The participants in the control group will obtain a conventional physiotherapy program. The conventional program includes: Appling transcutaneous electrical nerve stimulation (TENS), burst mode, with pulse width of 100 μs with a duration of 20 minutes and a frequency of 2 Hz [20] while hot-pack 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]. All the therapeutic actions in the study groups will be performed by an expert physiotherapist. The patient will be asked to do exercises. The set of the recommended exercises for participants are depicted in Table I.

Table I. 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

Recommended exercises for participants of the present study are as follow:

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

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

Lift one-foot 2cm while the pelvic 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 of their feet about 2cm from the ground.

Co-contraction of multifidus and transverse abdominis: The patients will be asked to lie in the prone position, with feet on the pillow and knees flexed. After, they will be asked to contract the transverse abdominis like in the first exercise and slowly contract the multifidus.

Head and shoulder lift on the elbow: The patients will be asked to flex their knees with the pelvis in a neutral position, and then lift their shoulder and head and hold 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 separated on both ischial tuberosity and the spine in a neutral position.

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

Erector spine stretch: The patients will be asked to sit on their knees, flexing the trunk and stretching the arms forward.

Intervention group

The patients in the intervention group will benefit from the conventional physiotherapy program. They also will receive 6 sessions of iliopsoas DN on the 1st, 3rd, 5th, 7th, 9th, and 10th sessions at the same time with their conventional physiotherapy program [20]. To perform the DN technique, patients will be asked to lie supine on a bed and slightly abduct the hip on the affected side. 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, with dimensions: 60 mm × 0.25 mm, Korea). 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 place of MTrP is set with palpable or visible LTR. This technique is stoped when no further LTR is elicited and the needle will 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 variables of participants in the control and treatment groups will be assessed at baseline and after completing the study procedure. Diagnosing the MTrP and the assessments will be performed by a professional physiotherapist having 15 years of experience in diagnosing and treating the issues related to MTrP and musculoskeletal dysfunctions. Fig 2 shows the SPIRIT study timeline for stages of the study.

Primary outcome measures

(1) LBP intensity

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

(2) Pain intensity at MTrP of the iliopsoas muscle

Alongside back pain intensity, the pain intensity at MTrP of the iliopsoas muscle will also be measured. For measuring this variable, the constant pressure of 2.5 kg/cm^2 will be applied to the MTrP with a digital algometer (FDX 50 force Gauge, Wagner Instruments, The USA) and maintained for 3 seconds. After that, the patients will be requested to report the pain intensity that they sense by using the NPRS scale.

Secondary outcome measures

(1) Functional disability

Quebec back pain disability scale will be used to measure the level of functional disability for people with LBP [27]. In this study, the Persian version of Quebec back pain disability Scale will be used. The questionnaire has shown excellent test-retest reliability (intra class correlation coefficient: 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 like getting out of bed, and taking out something from the refrigerator. With a rating from 0 (no effort) to 5 (unable to do), the participants will answer each question. The higher score represents much more disability [28, 29].

(2) Anxiety and depression

There is a close and mutual relationship between occurring CLBP and altering 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]. HADS is a suitable screening tool for assessing these variables in

clinical practice [32]. This questionnaire has 7 questions for anxiety and 7 questions for depression. The answer to each question is based on scoring from 0 to 3. The higher HADS score represents 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 to 21.

(3) PPT

The evaluation of PPT will be done using the digital algometer (FDX 50 force Gauge, Wagner Instruments, The 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 person is requested to report the exact time the feeling of pressure changes into pain and the amount of pressure will be recorded [34]. The PPT will be measured 3 times each time with a resting interval between ten seconds report [35].

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 by sending an email 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 Pair T-test will be used, respectively for comparison of the variables between the first and the tenth sessions, in the control and intervention groups, and between the two groups. The significant result 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 the subgroup analysis to improve our understanding of treatment efficacy and offer more detailed insights into our findings.

Anticipated results

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

Discussion

CLBP is a complex issue that can have various origins like the malfunction of muscles in the lumbar area (35). The iliopsoas muscle is an important muscle involved in many daily activities [9] and its normal function needs extra consideration. Development of MTrP in lumbopelvic muscles special 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 force on the spine and the restoration of its length is necessary [9]. Several studies have reported the effectiveness of iliopsoas muscle release with muscle energy technique (MET), stretching, and proprioceptive neuromuscular facilitation in improving the range of motion and other symptoms in LBP patients [10,11]. DN is a novel technique for the treatment of MTrP and could lead to the rapid elimination of pain, reduction of muscle stiffness, and muscle elongation [18,19]. Comparing the effectiveness of DN and MET in the release of quadratus lumborum muscle, it has also been reported that DN is more efficient in improving the symptoms of such patients with LBP compared to MET [36]. It seems that incessant inputs of the muscles afflicted by MTrP could lead to neuro-plastic alterations in the dorsal horn of the spinal cord and the 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, induces of the LTR in DN may have mechanical effects. Indeed, LTR leads to localized stretch to the contractured cytoskeletal structures and as a result, it causes a mechanical disruption of MTrP in the muscle [39]. Furthermore, based on previous studies, biochemical substances in active MTrPs are different compared to the normal sites of the muscle [40]. Alterations in

intramuscular blood circulation and decreasing the level of chemical substances like substance P and calcitonin-generated peptide in the MTrPs region could be due to the biochemical changes after the application of dry needling and may explain the therapeutic effects of DN on pain alleviation around 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], the evidence on applying the DN on MTrP of iliopsoas muscle is scarce [19-21]. Consequently, this study has aimed to determine the impact of the MTrP-DN in 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 will improve the functional ability and the quality of life of patients with CLBP.

There are some limitations in this study. First, although the researchers decided to investigate the sheer effect of MTrP-DN on the iliopsoas in patients with CLBP, the presence of MTrPs in other muscles, such as multifidus, the gluteus medius, and quadratus lumborum may mimic the symptoms and affect the results. Designing future studies with appropriate inclusion criteria (without the presence of MTrPs in other lumbopelvic muscles) may be a controller 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 the blinding of participants or DN performers is challenging. It is assumed that considering sham-DN treatment with toothpick Steinberger needle for the control group could help assess the placebo effect of releasing the muscle with DN.

Adverse events

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

Table II. 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

Conflicts of interest

The authors declared no Conflicts of interest.

Study sponsor and funder

Although this study will be conducted under the supervision of the Rehabilitation Sciences faculty at University of Medical Sciences, the study team will not receive any funding from the university or any other organization for any stages of the study.

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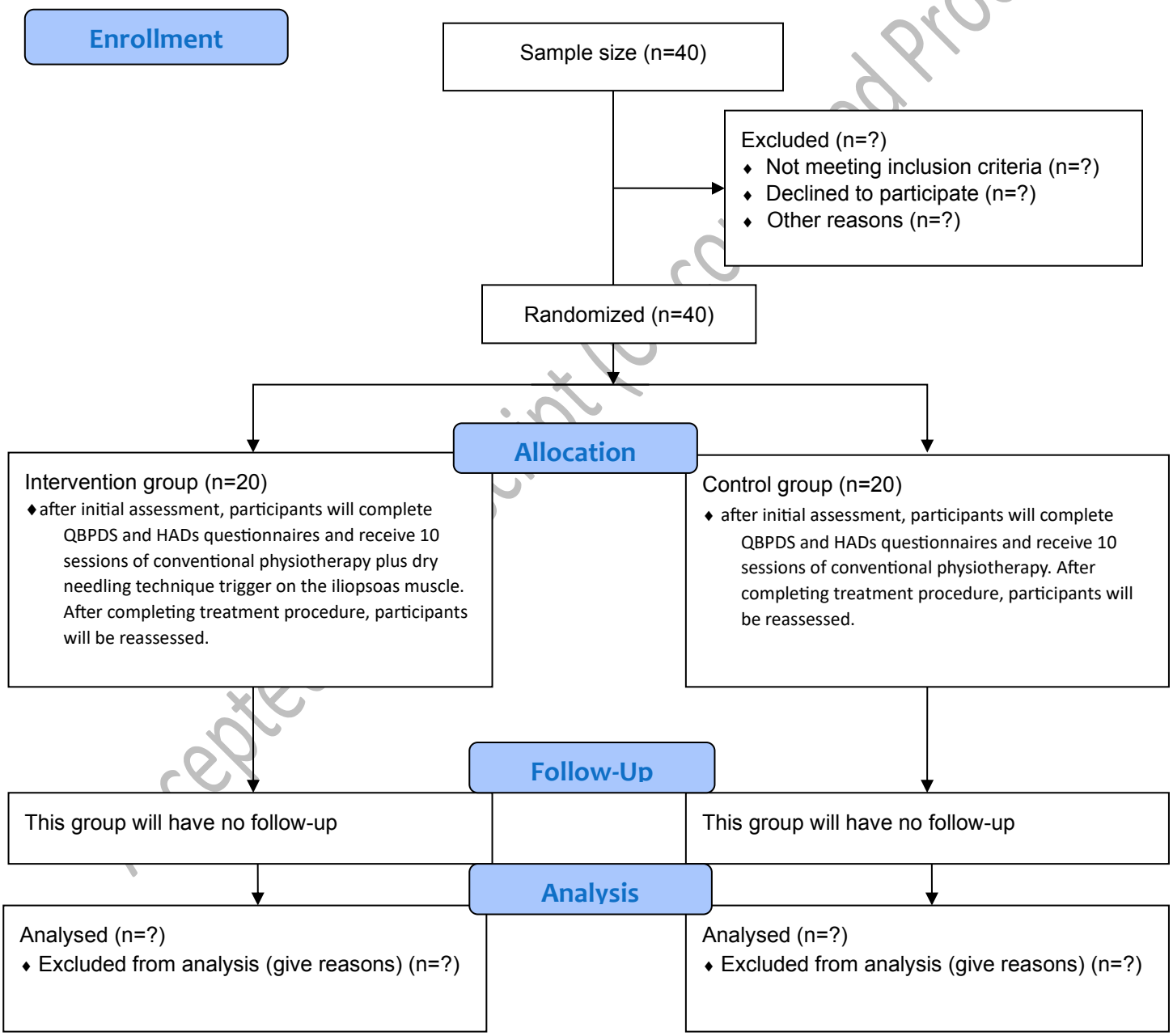

Fig 1: CONSORT flow diagram of the current study.

	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

Fig 2: Study timeline according to the SPIRIT checklist recommendation. 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.