Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of a four-steps programme on pain, functional disability, and postural control in elite athletes with chronic non-specific low back pain; a randomized controlled trial

Protocol summary

Study aim

Investigating the effect of a four-steps treatment programme on pain, functional disability, and postural control in elite athletes with chronic non-specific low back pain referred to an orthopedic physiotherapy clinic in Tehran in 2026.

Design

This study has an intervention group and a control group. The CONSORT checklist will be used to report the results in writing the thesis text.

Settings and conduct

In order to use laboratory equipment to assess condition control, the research location will be the Rehabilitation Research Center, Faculty of Rehabilitation, Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of chronic non-specific low back pain Elite athlete: An elite athlete is someone who exercises more than 10 hours per week and has reached the highest level of competition. Age between 18 and 55 No evidence of visible structural lesion on imaging Understanding and ability to follow instructions and fully cooperate during the study Not participating in any similar exercise or treatment program in the last 6 weeks. Exclusion criteria:Presence of specific spinal injuries Presence of neurological or systemic diseases History of surgery in the back or lower extremities within the past year Continuous use of anti-inflammatory or muscle relaxant medications during the study Pregnancy or menstruation in the acute phase Failure to complete treatment sessions or insufficient cooperation during the intervention period or assessments New injury or acute pain Severe motion artifacts or technical problems in IMU data

Intervention groups

The intervention group will receive myofascial release therapy, taping, and exercise after testing. The control group will receive sham myofascial release and taping, along with the same exercises as the intervention group, after testing.

Main outcome variables

Pain and Functional Disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260521069477N1**
Registration date: **2026-06-11, 1405/03/21**
Registration timing: **retrospective**

Last update: **2026-06-11, 1405/03/21**
Update count: **0**

Registration date

2026-06-11, 1405/03/21

Registrant information

Name

Alireza Yaseri Gohari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-23, 1405/03/02

Expected recruitment end date

2026-05-30, 1405/03/09

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of a four-steps programme on pain, functional disability, and postural control in elite athletes with chronic non-specific low back pain; a randomized controlled trial

Public title
The effect of a four-steps treatment programme in the treatment of athletes with low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of chronic non-specific low back pain: Pain or discomfort in the area between the twelfth rib and the inferior gluteal fold that has been present for at least 3 consecutive months and for which a specific origin (such as a herniated disc or fracture) has not been identified. Elite athlete: An elite athlete is someone who exercises more than 10 hours per week and whose athletic performance has reached the highest level of competition (e.g., members of a regional or national team, Olympic athletes, professional athletes, and some college athletes). Age between 18 and 55 No evidence of visible structural lesion on imaging (MRI or X-ray): The diagnosis of chronic nonspecific low back pain is made solely based on clinical criteria and exclusion of specific injuries. Understanding and ability to follow instructions and fully cooperate during the study (signing an informed consent form and sufficient familiarity with Persian or English). Not participating in any similar exercise or treatment program in the last 6 weeks.
Exclusion criteria:
Presence of specific spinal injuries such as herniated discs, spondylolisthesis, vertebral fractures, or spinal infections Presence of neurological or systemic diseases (such as multiple sclerosis, peripheral neuropathy, uncontrolled diabetes) that can affect postural control or pain perception History of surgery in the back or lower extremities within the past year Continuous use of anti-inflammatory or muscle relaxant medications during the study Pregnancy or menstruation in the acute phase (for female participants) due to hormonal changes affecting postural control Failure to complete treatment sessions or insufficient cooperation during the intervention period or assessments (more than two missed sessions) New injury or acute pain during the intervention that makes it impossible to continue participating in the study Severe motion artifacts or technical problems in IMU data that make data analysis impossible
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a phase III (superiority) single-center, randomized controlled clinical trial with a 1:1 randomization ratio. To reduce selection bias and ensure a uniform distribution of participant characteristics across study groups, a block randomization method with a block size of 4 will be used. The sequence of randomization will be determined by an independent investigator (not involved in the assessment and treatment process) using Random Allocation Software (version 2.0). The randomization codes will be placed in opaque, sealed envelopes and opened in the order in which subjects enter the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the study design and the presence of an intervention group and sham treatment, sham interventions will be administered in a manner as similar as possible to the intervention group so that participants feel the same way about the duration of treatment, therapist placement, and taping (kinesio taping), and are blinded to whether their treatment is real or not. In order to reduce bias, allocation concealment and blinding of participants will be performed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Rehabilitation Sciences, Iran University of Medical Sciences
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Tehran, Mirdamad, Madar Square, Shah Nazari Street, Madadkaran Street, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences
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Approval date
2026-05-20, 1405/02/30
Ethics committee reference number
IR.IUMS.REHAB.REC.1405.008

Health conditions studied

1

Description of health condition studied
Chronic Non-specific Low Back Pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Before and After Treatment
Method of measurement
Visual Analog Scale

2

Description
Functional Disability
Timepoint
Before and After Treatment
Method of measurement
Oswestry Disability Index - Iranian Version

Secondary outcomes

1

Description
Kinematic parameters of postural control
Timepoint
Before and After Treatment
Method of measurement
Inertial Measurement Unit data

Intervention groups

1

Description
Intervention group: The intervention will be carried out for 6 weeks, with two sessions per week (each session approximately 45 to 60 minutes) and at least 48 hours between sessions. The intervention phases in the four-phase group of the four-phase treatment (Test–Trigger–Tape–Train) are based on specific assessment, tissue release, movement modification and exercise training. This method is designed to improve postural function, reduce pain and functional disability in patients with chronic non-specific low back pain. 1. Test phase (functional and structural assessment) At the beginning of each session, the participant stands upright. During the baseline test, maximum forward bending of the trunk and maximum straightening of the trunk are performed to record baseline values of pain intensity. The most painful trunk movement (highest VAS pain score) is selected as the reference test and the direction that causes the least pain will be considered as the preferred direction (lowest VAS pain score). The reference test is used to examine the effect of skin and underlying fascia displacement on VAS pain and range of motion. The SKD itself will consist of four steps. (1) A lumbodorsal SKD will be performed in a medial-lateral direction to the right and left at the level of the L3, S2, T12, T9, and T4 vertebrae. Next, (2) an oblique SKD will be performed in a cephalo-caudal direction over the latissimus dorsi muscle. Then, (3) an anterior-posterior SKD over the ilium, and finally (4) a cephalo-caudal SKD over the lumbar spine. The severity of the SKD is greater than the degree of laxity of the skin and underlying fascia, equivalent to a grade 4 on the Maitland Passive Tissue Tension Rating Scale. The direction of the SKD that resulted in the most significant improvement in terms of VAS pain reduction and trunk range of motion will be selected as the “positive” direction and will be considered the best Trigger and Tape direction. After performing the Test, Trigger and Tape in one segment, then the steps are performed in the next segments and different SKD directions and we continue the steps until we have the best result. It should be noted that when the reference test without SKD showed the most positive result in terms of pain and/or trunk range of motion, “no intervention” is necessary in that location. 2. Trigger phase (myofascial release) At the desired location, a set of Triggers is applied, in a standing position with slight forward bending (approximately 60 degrees) and posterior rotation of the pelvis, while the patient is leaning forward towards the physiotherapy table. Then the fascia and muscle release is performed using the fist and adduction method. Next, spinal mobilization (grade 4) is performed to mobilize the spine in the preferred direction and the positive direction of SKD. While the patient is in a standing position, the inner part of the palm is placed in the posterior arch and the fifth finger will be placed approximately on the transverse process of the affected segment. The physiotherapist will assess the degree of laxity of the spine in the direction of SKD and ask the patient to take a deep breath, then hold the breath for 4 seconds. During exhalation, joint mobilization will be performed by moving the affected segment in the direction of SKD, which is held for 4 seconds and repeated 4 consecutive times. After spinal mobilization, elastic tape will be applied in the positive medial-lateral SKD direction at L3 while the patient is bent forward towards the physiotherapy table. 3. Tape Phase (Sports Taping) Sports taping will be applied in the positive SKD direction with the fascia displacement technique using approximately 20 cm of elastic tape (At Sport Tape®). For example, at the L3 level, the beginning (¼) of the elastic tape will be applied to the skin approximately 7 cm in the direction lateral to the L3

spinous process. The skin and underlying fascia are then simultaneously applied with the elastic tape (¾) with medium-high pressure in the opposite direction, with the aim of aligning, displacing and stretching the tissues under the tape in the direction of the SKD. The reference test with the tape will then be repeated to assess the effect of the fascial release techniques. The entire procedure will then be performed at the next site (test, trigger and tape) until the most painful direction of trunk movement reaches the acceptable pain level required to perform the exercise. 4. Train phase (functional exercises and postural control) Exercises are performed in the positive direction with the least pain obtained from the baseline test (preferred direction). The total training time is 30 minutes. The training program consisted of a 10-minute warm-up followed by muscular endurance training, muscular strength resistance training, flexibility training, and motor control training. The exercises were divided into 2 programs in the preferred direction: (1) a forward bending training program, which included the recumbent bicycle, Pilates Child pose, and Pilates Half rollback; or (2) a straight training program, which included the Crosstrainer, Pilates Low or High Puppy, and Pilates Breaststroke. A 60-second rest period was included between sets, as recommended by Schoenfeld et al.

Category
Rehabilitation

2

Description
Control group: Control group: For participants in the sham four-step treatment group, myofascial release and taping will be performed sham and they will only perform the exercises of recumbent bicycle, half rollback (Pilates), child pose (Pilates), stationary bicycle, breaststroke (Pilates), low or high puppy (Pilates), and crosstrainer. The duration, number of sessions, and supervision are the same in both groups to control for the variable effect of time and therapist focus.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person
Alireza Yaseri Gohari

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohammadreza Pourahmadi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Raw research data and its analysis will be made available to researchers upon request.

When the data will become available and for how long
After 6 months from the date of publication

To whom data/document is available
The data will be available to physiotherapists working on low back pain in academic organisations as well as in the clinic.

Under which criteria data/document could be used
The raw data and results of this study can be used for future systematic reviews. Therefore, the raw data and results of this study will be available to researchers working in the field of low back pain.

From where data/document is obtainable
Applicants can contact physiotherapist Alireza Yaseri Gohari via email. Email address: ayaseript@gmail.com

What processes are involved for a request to access data/document
Applicants should explain in detail about their project and how the data/documents from this study will be used in their project. The data/document files will then be sent to the applicants via email upon request. This process may take 10-12 business days.

Comments