

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the immediate effect of releasing trigger points of the upper trapezius muscle with and without kinesiotyping on pain, disability, range of motion and proprioceptive sensation in people with non-specific chronic neck pain

Protocol summary

Study aim

Comparison of the Immediate Effects of Upper Trapezius Trigger Point Release With and Without Kinesiotaping on Pain, Disability, Range of Motion, and Proprioception in Individuals With Chronic Nonspecific Neck Pain

Design

A randomized, double-blind, parallel-group, controlled clinical trial with pre- and post-test implementation. The randomization will be done using the randomization.org website.

Settings and conduct

This study will be conducted at the Islamic Azad University, Karaj Branch, and the university laboratory will be used to carry out the procedures. A double-blind design will be employed, in which both the outcome assessors and the statistical data analysts will be blinded to the type of intervention and group allocation. The intervention will be implemented by a team separate from the assessment team.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The presence of a palpable taut band in the muscle, with a small localized area of tightness in the center of the muscle fibers that is painful upon pressure. Exclusion Criteria: Any type of abnormality or injury that could affect the course of the study.

Intervention groups

Group 1 (Control): No intervention. Group 2 (Tennis Ball Release): Participants applied pressure to the upper trapezius trigger point using a tennis ball while lying supine with knees bent and pelvis lifted. The exercise was done for 1 minute, three times per side, with 30-second rests. Group 3 (Tennis Ball Release + Kinesiotaping): Same technique as Group 2, followed by kinesiotaping: Space correction: X-shape with 30% stretch. Muscle inhibition: From acromion to upper spine with 25% stretch.

Main outcome variables

Pain intensity; Functional disability; Proprioception; Range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240907062968N6**

Registration date: **2025-05-18, 1404/02/28**

Registration timing: **prospective**

Last update: **2025-05-18, 1404/02/28**

Update count: **0**

Registration date

2025-05-18, 1404/02/28

Registrant information

Name

Ali Honarvar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-26, 1404/03/05

Expected recruitment end date

2025-06-10, 1404/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the immediate effect of releasing trigger points of the upper trapezius muscle with and without kinesiotyping on pain, disability, range of motion and proprioceptive sensation in people with non-specific chronic neck pain

Public title

Immediate effect of trigger point release of the upper trapezius muscle with and without kinesiotaping

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Presence of a palpable, tight band in the muscle. A small knot in the center of a muscle fiber that is painful to the touch.

Exclusion criteria:

Any type of abnormality or damage affecting the research process

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be web-based. Subjects who meet the inclusion criteria for the study will be randomly assigned to the first experimental group, the second experimental group, and the control group using the website randomization method (Social Psychology Network, Connecticut, USA) www.randomizer.org. The randomization will be simple. Concealment of the random allocation will be done using a computer-generated blocked randomization table, where number 1 is defined for the tennis ball release group, number 2 for the tennis ball release plus kinesiotape group, and number 3 for the control group. The random numerical sequence will then be placed in sealed, opaque envelopes. Also, according to the assignment of the groups, the intervention will be continued by the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, after reviewing the consent form in a 30-minute session, are informed about the study groups and participate willingly in this study without having the permission to choose a group. The patients' names are randomly divided into three equal groups by a person unaware of the individuals' identity and physical characteristics, using the website <http://randomizer.org>, and each part is placed separately in sealed envelopes. Then, each individual receives the corresponding training and exercises according to their assigned group. The analyst and outcome evaluator, without being aware of the hypotheses, study methods, and patients' characteristics, examines and compares the changes before and after eight weeks.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University Karaj branch

Street address

Karaj Branch, Islamic Azad University, Mo'azen Boulevard, Rajai Shahr, Karaj City Alborz Province

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Postal code

3149968111

Approval date

2025-05-10, 1404/02/20

Ethics committee reference number

IR.IAU.K.REC.1404.037

Health conditions studied**1****Description of health condition studied**

Upper trapezius trigger points

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain Measurement

Timepoint

Before and after the intervention

Method of measurement

To assess pain, the Visual Analog Scale (VAS) is used. This scale is a 10-centimeter line that represents overall pain and is graded from zero (no pain) to 10 (severe pain). Scores of 1-3 indicate mild pain, 4-6 moderate pain, and 7-10 severe pain. The validity and reliability of VAS in pain measurement are very high, and its reliability has been reported as 0.92.

2

Description

Functional disability

Timepoint

Before and after the intervention

Method of measurement

To assess functional disability, the Neck Pain and Disability Index will be used. This self-administered, validated index includes 20 sections and four dimensions (neck pain intensity, disorders caused by it, emotional effects, and interference with daily activities). The score of each index is between 0 and 5, and the total score is calculated by dividing the sum of the scores by 10 (0=no pain, 10=maximum pain). The validity of this questionnaire is reported to be good to high, and its reliability is reported with a Cronbach's alpha of 0.86. Also, the intra-cluster correlation of the questionnaire was obtained as 0.93 using the test-retest method.

3

Description

Range of motion

Timepoint

Before and after the intervention

Method of measurement

The range of motion for neck flexion is measured with a goniometer. The subject sits on a chair with spinal support, with their head and neck in the anatomical position. The axis of the goniometer is placed on the external auditory canal, the fixed arm is perpendicular to the ground, and the moving arm is placed on the surface of the nose. The subject is asked to flex their neck forward as much as possible, and the goniometer reading is recorded. This test is repeated twice, and the average is recorded as the final score.

4

Description

Proprioception

Timepoint

Before and after the intervention

Method of measurement

To assess head position sense, the head-neck repositioning test was used, measuring angular repositioning error using a laser pointer. Thus, the subject was seated 90 cm away from the wall on an armless chair with a high back, feet on the ground, and palms on their legs. A laser pointer fixed to a plastic headband was attached to the highest point of the subject's head. An eye mask was used to eliminate

vision. The subject was asked to place their head in a natural and comfortable position, and the laser light was marked by the examiner as a reference point on a white paper mounted on the wall in front of them. Focusing on the reference point, the subject performed a complete head extension movement in the sagittal plane and then a rotational movement to the right in the horizontal plane at a slow speed, trying to return the head to its initial position. The position of the laser light was marked by the examiner on the screen, and its distance from the reference point was determined in centimeters, and the amount of angular repositioning error was calculated using the appropriate formula. The test was performed with one trial repetition and three main repetitions for each direction. This method has high validity ($R=0.87$), and research has shown that this method has a high correlation ($R=0.95$) with ultrasound technology in the simultaneous measurement of head position sense.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Trigger point release with a tennis ball: For this method, the patient lies on their back with knees bent and feet flat on the floor, moving the tennis ball over the affected area to find the trigger point. Then, by lifting the hips, pressure is applied to this point. This movement is repeated three times on each side, each time for one minute with 30 seconds of rest. The entire session lasts 15 minutes and includes three repetitions on each side.

Category

Rehabilitation

2

Description

Intervention group 2: Intervention group: Release of trigger points in the upper trapezius muscle with a tennis ball plus the use of kinesiotape in two methods: 1) Space correction: directly over the painful point in a criss-cross pattern with 30% tension. 2) Muscle inhibition: from below the acromion process to the hairline with 25% tension. The control group will receive sham kinesiotape (similar in appearance but without tension) to eliminate psychological effects, with no intervention.

Category

Rehabilitation

3

Description

Control group: Without intervention, just perform the tests.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad university Karaj Branch

Full name of responsible person

Ali Honarvar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Maleki

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Vahid Mazloun

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

The data related to the subjects of the control and intervention groups in the pre-test and post-test are shared in an unidentifiable way.

When the data will become available and for how long

Data access is available six months after the publication of the articles.

To whom data/document is available

The data will be available for physiotherapists working in academic institutions, as well as clinicians working in the field of musculoskeletal disorders, and all researchers. Use of the data is permitted with source citation.

Under which criteria data/document could be used

The raw data and results of this study may be used in systematic review studies. Therefore, the raw data and results of this study will be accessible to researchers who are active in the field related to this study.

From where data/document is obtainable

Via email Vahid.mazloun@yahoo.com

What processes are involved for a request to access data/document

Applicants must precisely explain their project and how the data/documents of this study will be used in their project. Subsequently, the data/document files will be sent to the applicants via email following the request. This process may take 10-12 business days.

Comments