

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 26 3443 4073

##### Email address

alihonarvar144@gmail.com

##### 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](http://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

**City**

Karaj

**Province**

Alborz

**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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info@kiau.ac.ir

## 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

**Street address**

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

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**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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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.mazloum@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**