

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of upper trapezius muscle kinesiotype combined with Swedish massage on neck pain disability index, neck range of motion, quality of life, deep neck muscle function index and forward head angle in women with chronic neck pain

#### Protocol summary

##### Study aim

The aim of this study is to determine the effect of upper trapezius muscle kinesiology taping combined with Swedish massage on the Neck Pain Disability Index, Neck Range of Motion, Quality of Life, Deep Neck Muscle Function Index, and Forward Head Angle in women with chronic neck pain.

##### Design

This study is a randomized controlled trial (RCT) with parallel groups. Participants will be randomly assigned to two groups using Excel software (RAND function): intervention group (kinesiotaping and Swedish massage) and control group (usual care or placebo). The sample size is set at 100 patients and the study will be conducted in phase 2.

##### Settings and conduct

This study was a randomized clinical trial conducted in the laboratory of the Faculty of Sport Sciences at Razi University, in a controlled environment using advanced equipment. Participants were randomly assigned to intervention and control groups. The intervention group received a combination of upper trapezius kinesiotaping and Swedish massage for eight weeks. Data were collected before and after the intervention using the Neck Disability Index (NDI), goniometer, and SF-36 questionnaire.

##### Participants/Inclusion and exclusion criteria

Participant inclusion criteria included: Having chronic neck pain for at least 3 months. Age between 20 and 50 years. Not receiving physical or drug treatments affecting the neck in the past 6 weeks. Participant exclusion criteria included: History of surgery or serious injury to the neck. Having advanced neuromuscular or inflammatory diseases.

##### Intervention groups

Intervention groups: 1. Kinesiotaping + Swedish

massage group: 2. Control group: - Receive usual care or sham intervention (if applicable) without kinesiotaping or Swedish massage.

##### Main outcome variables

Neck Pain Disability Index, Neck Range of Motion, Quality of Life, Deep Neck Muscle Performance Index, and Forward Head Angle

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250222064801N1**

Registration date: **2025-06-02, 1404/03/12**

Registration timing: **retrospective**

Last update: **2025-06-02, 1404/03/12**

Update count: **0**

##### Registration date

2025-06-02, 1404/03/12

##### Registrant information

##### Name

Sayede Maryam Hosseini Rad

##### Name of organization / entity

The University Razi of Kermanshah

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3723 2233

##### Email address

maryamhosseinirad1996@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2025-04-09, 1404/01/20

**Expected recruitment end date**

2025-05-10, 1404/02/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of upper trapezius muscle kinesiotype combined with Swedish massage on neck pain disability index, neck range of motion, quality of life, deep neck muscle function index and forward head angle in women with chronic neck pain

**Public title**

The effect of kinesiotyping and Swedish massage on chronic neck pain, range of motion and quality of life in women

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having chronic neck pain for at least 3 months. Age between 20 and 50 years. Not receiving any physical or pharmacological treatments affecting the neck in the past 6

**Exclusion criteria:**

History of surgery or severe injury in the neck area. Presence of advanced neuromuscular or inflammatory diseases. Pregnancy or having movement limitations unrelated to neck pain.

**Age**From **18 years** old to **40 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **28****Randomization (investigator's opinion)**

Randomized

**Randomization description**

For randomization in this study, a variable-size block method was used: first, with statistical software (such as SPSS), random sequences were generated in blocks of different sizes (e.g., 4 or 6), in which in each block, an equal number of participants were assigned to the "intervention" (receiving FA and Swedish massage) and "control" groups. These sequences were then sealed in opaque, numbered envelopes. After registering each participant, the researcher opened the corresponding envelope and identified the individual's group. This method increased the scientific validity of the study by ensuring a balance of groups (even in the event of sample withdrawal), preventing the researcher from

predicting allocation (reducing bias), and conducting it independently of the evaluation team, following CONSORT standards.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants will be kept unaware of their group assignment (intervention or control) by designing the content and structure of the interventions in both groups to be as similar as possible in terms of appearance, timing, and method of implementation. These similarities are intended to minimize the likelihood of participants identifying their group assignment and to prevent bias arising from their expectations. This approach helps enhance the validity of the study results and reduces potential biases.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Razi University of Kermanshah

**Street address**

No. 8, University Blvd, Kermanshah Province, Razi University

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

661489569

**Approval date**

2023-11-29, 1402/09/08

**Ethics committee reference number**

IR.RAZI.REC.1402.079

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

Chronic Neck Pain

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

Neck Pain Disability Index

### **Timepoint**

Before the intervention and after the end of the study

### **Method of measurement**

It is measured using the NDI questionnaire, which consists of 10 questions about pain intensity and functional limitations. Each question has a score between 0 and 5, and the total score is calculated between 0 and 50. A higher score indicates greater disability.

## **2**

### **Description**

Neck Range of Motion

### **Timepoint**

Before the intervention and after the end of the study

### **Method of measurement**

Using a goniometer or motion measurement devices (such as electronic systems or motion analysis software), the range of motion of the neck in different directions (forward bending, backward bending, left and right rotation, and lateral bending) is measured.

## **3**

### **Description**

Quality of Life

### **Timepoint**

Before the intervention and after the end of the study

### **Method of measurement**

It is measured using standard questionnaires such as the SF-36 (36-Item Short Form Health Survey) or WHOQOL-BREF. These questionnaires assess different dimensions of quality of life, including physical, mental, social, and environmental health.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Kinesiotape plus Swedish massage. This group will receive a combination of two interventions: Kinesiotape: on the upper trapezius muscle to improve muscle function and reduce pain. Combined with Swedish massage to reduce muscle tension and improve blood circulation in the neck area. This combination is designed to increase the effectiveness of the treatment and improve symptoms faster.

#### **Category**

Prevention

### **2**

#### **Description**

Control group: This group will receive Swedish massage only. Swedish massage is used alone to reduce pain, improve range of motion, and relax the neck muscles. The aim of this group is to examine the effect of Swedish

massage alone, without the combination of Kinesiotape.

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Razi University of Kermanshah

##### **Full name of responsible person**

Manouchehr Heydari

##### **Street address**

No. 9, University Blvd, Kermanshah Province, Razi University of Kermanshah

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##### **Postal code**

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##### **Phone**

+98 83 3428 3270

##### **Email**

mhaidary2000@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Razi University of Kermanshah

##### **Full name of responsible person**

Kianoosh Chaghamirza

##### **Street address**

No. 9, University Blvd, Kermanshah Province, Razi University of Kermanshah

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##### **Email**

Kianoosh.Chaghamirza@Razi.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Razi University of Kermanshah

#### **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**

Razi University of Kermanshah

**Full name of responsible person**

Manouchehr Heydari

**Position**

Assistant Professor of Sports Pathology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sports Pathology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Razi University of Kermanshah

**Full name of responsible person**

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**Position**

Assistant Professor of Sports Pathology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sports Pathology

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**Person responsible for updating data****Contact****Name of organization / entity**

Razi University of Kermanshah

**Full name of responsible person**

Maryam Hosseini Rad

**Position**

Master's Degree

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports Pathology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data will be recorded in SPSS and can be presented.

**When the data will become available and for how long**

Access begins 9 months after the publication of all articles

**To whom data/document is available**

Only available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

All data can be used for citation.

**From where data/document is obtainable**

Maryam Hosseini Maryamhosseini1996@gmail.com

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

The process of receiving documents or data files includes the steps of registering the request, reviewing and approving it, preparing the data, sending it, and following up. First, the requester completes the request form (15

to 30 minutes), then the request is reviewed by the study researchers and, if necessary, additional information is requested from the requester (1 to 3 business days). After approval, the data is prepared and its quality is checked (2 to 5 business days). The data is sent electronically or physically, with electronic sending taking place immediately and physical sending taking 2

to 7 business days. Finally, the study researchers respond to any questions within 1 to 2 business days. The overall time to receive data varies between 4 and 15 business days depending on the type of request and the method of submission.

**Comments**