

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of combined pilates-Kinesio tape and mulligan-Kinesio tape exercises tape on pain, hamstring stiffness, lumbar range of motion, and pelvic tilt in women of nonspecific chronic low back pain

#### Protocol summary

##### Study aim

Comparison of combined pilates-Kinesio tape and mulligan-Kinesio tape exercises tape on pain, hamstring stiffness, lumbar range of motion, and pelvic tilt in women of non-specific chronic low back pain

##### Design

A clinical trial study with parallel groups, open-labeled and phase 3, which will be conducted on 30 participants. Randomization will be done by simple randomization using random numbers table.

##### Settings and conduct

Women who will be referred for the treatment of low back pain in the orthopedic clinic of Urmia Imam Khomeini Hospital will be included. The study will be an open-label study.

##### Participants/Inclusion and exclusion criteria

In this study, women with non-specific chronic low back pain will be included. The inclusion criteria will be including persistent back pain for at least 12 weeks; age between 35 to 65 years old; pain intensity between 3-6 based on the visual analogue scale (VAS) and difficulty in bending forward. Participants with pregnancy, narrowing of the canal, lumbar disc, tumor, history of spine surgery, rheumatoid arthritis, and osteoporosis will be excluded.

##### Intervention groups

Participants in group one will do Pilates exercises three days a week for 6 weeks (one hour each time). The exercises will be 6 to 8 repetitions in the first sessions and 10 to 12 repetitions in the last sessions. In the second group, the participants will receive Mulligan techniques three days a week for 6 weeks (one hour each time), the exercises will be performed with 3 repetitions in the first sessions and 10 repetitions in the last sessions.

##### Main outcome variables

Pain; hamstring stiffness; lumbar range of motion and pelvic tilt

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211228053554N3**

Registration date: **2022-09-11, 1401/06/20**

Registration timing: **prospective**

Last update: **2022-09-11, 1401/06/20**

Update count: **0**

##### Registration date

2022-09-11, 1401/06/20

##### Registrant information

##### Name

siyamak kazemisofi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3345 9538

##### Email address

kazemisofi.s@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-23, 1401/08/01

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of combined pilates-Kinesio tape and mulligan-Kinesio tape exercises tape on pain, hamstring stiffness, lumbar range of motion, and pelvic tilt in women of nonspecific chronic low back pain

## Public title

The effect of combined pilates-Kinesio tape and mulligan-Kinesio tape exercises on nonspecific chronic low back pain

## Purpose

Other

## Inclusion/Exclusion criteria

### Inclusion criteria:

Persistent back pain for at least 12 weeks Age between 35 to 65 years Pain intensity is between 3-6 based on the visual analogue scale (VAS) Difficulty in bending forward

### Exclusion criteria:

Pregnancy Narrowing of the canal Lumbar disc Tumor History of spine surgery Rheumatoid Arthritis Osteoporosis

## Age

From **35 years** old to **65 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will be randomly divided into groups using a table of random numbers.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Allameh Tabatabai University

##### Street address

Allameh Tabatabai University., Village Square., Olympic Village., Tehran., Iran.

##### City

Tehran

##### Province

Tehran

#### Postal code

1489684511

#### Approval date

2022-06-28, 1401/04/07

#### Ethics committee reference number

IR.ATU.REC.1401.024

## Health conditions studied

### 1

#### Description of health condition studied

Chronic low back pain

#### ICD-10 code

M54.5

#### ICD-10 code description

Low back pain

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before and 6 weeks after the intervention

#### Method of measurement

visual analogue scale (VAS)

### 2

#### Description

hamstring stiffness

#### Timepoint

Before and 6 weeks after the intervention

#### Method of measurement

Straight Leg Raise (SLR) test

### 3

#### Description

Lumbar range of motion

#### Timepoint

Before and 6 weeks after the intervention

#### Method of measurement

Inclinometer

### 4

#### Description

Pelvic tilt

#### Timepoint

Before and 6 weeks after the intervention

#### Method of measurement

Tilt meter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Participants in group one will do Pilates exercises three days a week for 6 weeks (one hour each time). The exercises will be 6 to 8 repetitions in the first sessions and 10 to 12 repetitions in the last sessions.

#### Category

N/A

### 2

#### Description

Intervention group: In the second group, the participants will receive Mulligan techniques three days a week for 6 weeks (one hour each time), the movements will be performed with 3 repetitions in the first sessions and 10 repetitions in the last sessions.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Orthopedic Clinic of Urmia Imam Khomeini Hospital

##### Full name of responsible person

Dr. Siamak Kazemi Sofi

##### Street address

Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

57157-89397

##### Phone

+98 44 3345 7286

##### Email

kazemisofi.s@umsu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Saber Gholizadeh

##### Street address

Urmia University of Medical Sciences., Resalat Ave., Jahad Blvd., Urmia., Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3223 4897

##### Email

gholizadeh.s@umsu.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Siamak Kazemi Sofi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

57157-89397

##### Phone

+98 44 3345 7286

##### Email

kazemisofi.s@umsu.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Siamak Kazemi Sofi

##### Position

Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
Imam Khomeini hospital., Ershad Ave., Modarres  
Blvd., Urmia., Iran.  
**City**  
Urmia  
**Province**  
West Azarbaijan  
**Postal code**  
57157-89397  
**Phone**  
+98 44 3345 7286  
**Email**  
kazemisofi.s@umsu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Oroumia University of Medical Sciences  
**Full name of responsible person**  
Dr. Siamak Kazemi Sofi  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
Imam Khomeini hospital., Ershad Ave., Modarres  
Blvd., Urmia., Iran.  
**City**  
Urmia  
**Province**

West Azarbaijan  
**Postal code**  
57157-89397  
**Phone**  
+98 44 3345 7286  
**Email**  
kazemisofi.s@umsu.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### 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

The results will be available as the published article.

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

After publishing the article

### To whom data/document is available

Researchers

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

Not applicable

### From where data/document is obtainable

Email address of the corresponding author

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

Email address: kazemisofi.s@umsu.ac.ir

### Comments