

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

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57157-89397

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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.

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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

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Person responsible for scientific inquiries

Contact

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Oroumia University of Medical Sciences

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Position

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Latest degree
Specialist
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

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