

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of exercise therapy with VR on sensory, psychosocial symptoms, and electromyographic activity of trunk muscles during functional tasks in chronic low back pain patients with high central sensitization.

Protocol summary

Study aim

This study focuses on central sensitization in back pain and evaluates virtual reality (VR) as a potential therapeutic approach.

Design

In this single-blind randomized clinical trial, patients are enrolled in the study based on the central sensitivity questionnaire and are first evaluated in two groups. Then, the group of patients with high central sensitivity undergoes intervention with virtual reality exercises for four weeks.

Settings and conduct

The study will be conducted as a randomized clinical trial, and eligible patients will be enrolled after screening and randomly assigned to intervention and control. The interventions will then be implemented during specific sessions, and variables such as pain intensity, disability, central sensitivity indices, and motor function will be assessed before and after the intervention.

Participants/Inclusion and exclusion criteria

Include: age 18-60, chronic low back pain, moderate pain, high central sensitization, normal cognition, and sensation. Exclude: disc/nerve pathology, systemic disease, pregnancy, high BMI, sensory or balance disorders, noncompliance, or inability to exercise.

Intervention groups

Subjects perform 30-45 minutes of Xbox 360 Kinect game-exercise with no prior Kinect use or professional intense exercise history. Each session includes 10 minutes of warm-up and 5 minutes of cool-down stretching. Exercise is done 3 m from the Kinect and a 48-inch monitor, with chair rest allowed if needed. Intensity is kept at 64-76% HRmax via fingertip monitoring. Games are selected from Kinect Adventures, and difficulty is adjusted by time or repetitions based on pilot results

Main outcome variables

Pain severity, psychosocial symptoms, degree of functional disability, central sensitization, motorfunction

General information

Reason for update

Acronym

CS (Central sensitization)

IRCT registration information

IRCT registration number: **IRCT20090203001637N14**

Registration date: **2026-02-11, 1404/11/22**

Registration timing: **prospective**

Last update: **2026-02-11, 1404/11/22**

Update count: **0**

Registration date

2026-02-11, 1404/11/22

Registrant information

Name

Sedighe Kahrizi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-11, 1405/01/22

Expected recruitment end date

2027-09-06, 1406/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of exercise therapy with VR on sensory, psychosocial symptoms, and electromyographic activity of trunk muscles during functional tasks in chronic low back pain patients with high central sensitization.

Public title

The effect of virtual reality exercise therapy in the treatment of chronic low back pain patients with high central sensitization.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of low back pain for at least 3 months as defined by the US National Institutes of Health as non-specific low back pain. Having an average pain intensity between 3 and 7 at the time of study entry Having a score of 40 or higher on the Central Sensitivity Questionnaire No pain medication for 48 hours prior to assessment and intervention. No abnormalities in skin sensation. Scoring above 23 on the Mini-Mental State Examination (MMSE).

Exclusion criteria:

Having intervertebral disc problems and nerve involvement (such as disc herniation, spondylosis, spondylolisthesis, and radiculopathy) and a history of any related surgery History of cardiovascular, respiratory, rheumatic, neurological, malignancy, and infection diseases Pain intensity higher than 7 and lower than 3 based on VAS on the day of the test Pregnancy Body mass index (BMI) higher than 25 kilograms per square meter Vision and hearing impairment Having a confirmed disorder of the vestibular and balance system Unwillingness to continue cooperation Inability to learn and correctly execute an exercise program Missing the inclusion criteria for the treatment period

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using sealed, numbered envelopes, each containing the group allocation. Participants will receive an envelope upon

enrollment, ensuring allocation concealment and minimizing selection bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

To prevent assessment bias, evaluators will be blinded to the patients' group allocation (intervention or control).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tarbiat modares University

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Tehran, Jalal Al-Ahmad, Nasr Crossing, Tarbiat Modares University

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Approval date

2025-11-01, 1404/08/10

Ethics committee reference number

IR.MODARES.REC.1404.136

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

non-specific low back pain (LBP) with high levels of central sensitization

ICD-10 code

central se

ICD-10 code description

central sensitization

Primary outcomes**1****Description**

Central Sensitization Questionnaire

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

Central Sensitivity Questionnaire, Persianized version

2

Description

Pain Pressure Threshold

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

Algometer

3

Description

pain

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

VAS

4

Description

Pain Catastrophizing

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

Persian version of the Pain Catastrophizing Questionnaire

5

Description

TSK Questionnaire

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

Persian version of the TSK Questionnaire

6

Description

Oswestry Disability

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

Persian version of the Oswestry Disability Questionnaire

7

Description

electromyographic activity of trunk muscles

Timepoint

One day before the start of the intervention and one day after the end of the intervention for four weeks (12 sessions)

Method of measurement

Surface Electromyography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Individuals in this group will play games and exercise with the Xbox 360 Kinect for 30–45 minutes and should not have a history of using the Kinect or engaging in strenuous professional exercise. Each session will include a 10-minute warm-up and 5-minute cool-down. Exercise will be performed at a distance of 3 meters from the device and a 48-inch screen, and rest will be allowed if fatigue occurs. Exercise intensity will be maintained at 64–76% HRmax by monitoring heart rate. Games will be selected from Kinect Adventures and intensity will be adjusted by changing time or repetitions as needed. If pain or disability increases, exercise will be stopped or the individual will be withdrawn from the study.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat Modares University

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tarbiat Modares University

Full name of responsible person

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Web page address**Grant name**

Research Deputy of Tarbiat Modares University

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy of Tarbiat Modares 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**

Tarbiat Modares University

Full name of responsible person

Behdokht Dehqan

Position

Student of PHD in Physical Therapy

Latest degree

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Other areas of specialty/work

Physiotherapy

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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
File of intervention program protocol and statistical analysis plan through publication of thesis and writingan article
When the data will become available and for how

long
Starting 6 months after publication of results
To whom data/document is available
The research team of this study and other clinical academic researchers who are studying in favor of these patients.
Under which criteria data/document could be used
Researchers who intend to write a meta-analysis or systematic review articles are allowed to access document.
From where data/document is obtainable
Sedighe Kahrizi ; Behdokht Dehqan
What processes are involved for a request to access data/document
The request will be responded after getting the approval of university or the academic institution
Comments