Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 ensitization)

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

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Sedighe Kahrizi
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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
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Sponsors / Funding sources

1

Sponsor
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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
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Full name of responsible person
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Position
Student of PHD in Physical Therapy

Latest degree
Master

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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