Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Acute Effects of XBOX 360 Kinect Exergames and Core Stability Exercises on Cognition Factors, Pain, Mood, Fatigue and Fear Avoidance Beliefs in People with Chronic Non-Specific Low Back Pain.

Protocol summary

Study aim

The present study aims to determine whether exergames can immediately enhance cognitive factors, perceived level of exertion due to exercising, mood states, and improvement of fear-avoidance beliefs and pain in subjects with CLBP. The treatment effectiveness of exergames will then be compared to regular core stability exercises.

Design

Randomized single-blinded clinical trial, with two interventional groups (exergames and core stability exercises), on 48 subjects with CLBP

Settings and conduct

Forty-eight subjects with non-specific CLBP based on inclusion/exclusion criteria participate. Participants are randomized into 2 interventional groups: XBOX 360 Kinect exergames or core stability exercises. Subjects in each group are blinded to the intervention of another group. Pre/post assessments and interventions take place in a single session. Cognitive factors (working memory and attention), pain, fear avoidance beliefs and mood will be assessed. Acute pre- to post-changes will be compared within each group and between both groups. In addition, the perceived level of exertion after exercise is assessed and compared between two groups.

Participants/Inclusion and exclusion criteria

All men and women aged between 25 and 40, who have a history of LBP for at least 3 months, cognitive impairments, 7>VAS≥3 during assessment and intervention and using no painkiller during previous 48h; include. Anyone with a history of spinal and underlying disease, pregnancy, BMI≥25 Kg/m2, visual-auditory and balance disturbance, disability in learning and performing the interventional program and previous experience of using Xbox Kinect; exclude.

Intervention groups

In the exergaming group, subjects play with XBOX 360 Kinect games. In the other group, subjects perform core stability exercises.

Main outcome variables

Working memory, Attention, Level of pain, Fear avoidance beliefs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090203001637N12**
Registration date: **2021-11-01, 1400/08/10**
Registration timing: **prospective**

Last update: **2021-11-01, 1400/08/10**
Update count: **0**

Registration date

2021-11-01, 1400/08/10

Registrant information

Name
Sedighe Kahrizi
Name of organization / entity
Tarbiat Modares University
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Acute Effects of XBOX 360 Kinect Exergames and Core Stability Exercises on Cognition Factors, Pain, Mood, Fatigue and Fear Avoidance Beliefs in People with Chronic Non-Specific Low Back Pain.

Public title
Acute effects of exergames on cognition in people with chronic non-specific low back pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
History of LBP for at least 3 months 7 > VAS ≥ 3 during assessment and intervention Not taking any painkillers 48 hours before the assessment and intervention Having cognitive impairments based on the scores of cognitive tests in matched healthy people Men and women between 25 and 40 years old

Exclusion criteria:
History of any spinal disease or related surgery History of cardiopulmonary disease, rheumatoid disease, and malignancy 3 > VAS ≥ 7 during the assessment and intervention BMI ≥ 25 Kg/m2 Pregnancy Visual or auditory disturbance Balance or vestibular impairments Disability in learning and performing the interventional program Previous experience of using Xbox 360 Kinect

Age
From **25 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the total sample size, a 48-digit random sequence is created using Online Randomization. The sequence of random numbers is then placed in opaque sealed envelopes, respectively. In order of arrival, subjects based on their envelope's number are randomly assigned to intervention one or intervention two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants are not aware of the allocation of study groups .Thus subjects of the two groups do not meet and assessments take place separately in even and odd days.

Placebo
Not used

Assignment
Parallel

Other design features
In both groups, pre-assessments, interventions and post-assessments take place in a single session.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tarbiat Modares University (T.M.U)

Street address
Medical Ethics Committee, Faculty of Medical Sciences,Tarbiat Modares University, Jalal Al Ahmad Highway

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Province
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1411713116

Approval date
2021-10-23, 1400/08/01

Ethics committee reference number
IR.MODAREC.REC.1400.199

Health conditions studied

1

Description of health condition studied
Chronic non-specific low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Working memory

Timepoint
Pre and post intervention

Method of measurement
N-Back software

2

Description
Attention

Timepoint
Pre and post intervention

Method of measurement
Simple Stroop test software

Secondary outcomes

1

Description
Level of pain
Timepoint
Pre and post intervention
Method of measurement
Visual analog scale (VAS)

2

Description
Fear avoidance beliefs
Timepoint
Pre and post intervention
Method of measurement
Tampa Scale of Kinesiophobia (TSK)

3

Description
Mood
Timepoint
Pre and post intervention
Method of measurement
The Brunel Mood Scale (BRUMS-32)

4

Description
Perceived level of exertion due to exercising
Timepoint
Post intervention
Method of measurement
BORG Rating of Perceived Exertion (RPE)

Intervention groups

1

Description
Exergaming group: A single exercise session (30-45 minutes, minimum to moderate intensity = 64-76% MAX HR) with Microsoft Xbox 360 Kinect games, will perform. 5 to 10 minuets in the beginning and ending of the session allocated to warm-up and cool-down.
Category
Rehabilitation

2

Description
Core stability exercising group: A single core stability exercise session (30-45 minutes, minimum to moderate intensity = 64-76% MAX HR) such as abdominal hollowing, bridges, plank holding, cat-camel, knee to chest, and quadruped core exercises, will perform. 5 to 10 minuets in the beginning and ending of the session allocated to warm-up and cool-down
Category
Rehabilitation

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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Grant name
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
Naghme Massah

Position
Student of M.sc in Physical Therapy

Latest degree
Bachelor

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 ; Naghme Massah, Randy Neblett

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