Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of relaxation-based virtual reality on the psychological indicators of athletes with knee injuries

Protocol summary

Study aim
To investigate the effect of virtual reality–based relaxation on psychological outcomes in athletes with knee injuries.

Design
This study is a randomized controlled, pretest–posttest trial. Thirty male athletes in the early phase of rehabilitation following anterior cruciate ligament reconstruction will be recruited through convenience sampling and randomly allocated (1:1) to either the intervention group or the control group using a computer-generated simple randomization sequence.

Settings and conduct
This study will be conducted at a physiotherapy clinic in Sari, Iran. Eligible participants will be randomly assigned to intervention or control groups, and psychological outcomes will be assessed before and after the intervention.

Participants/Inclusion and exclusion criteria
Male athletes aged 24–34 years who have undergone anterior cruciate ligament reconstruction and are in the early phase of rehabilitation will be eligible. Participants must have a history of regular exercise and be willing to complete the study. Individuals with concurrent injuries, severe pre-existing psychological disorders, poor adherence to the intervention, or absence from study sessions will be excluded.

Intervention groups
Control Group:Participants will receive routine physiotherapy alone, including electrotherapy, range-of-motion exercises, muscle strengthening, and functional rehabilitation exercises, without virtual reality–based relaxation. Intervention Group: Participants will receive routine physiotherapy combined with virtual reality–based relaxation. During physiotherapy sessions, participants will use virtual reality glasses to view immersive nature-based relaxation videos designed to promote psychological relaxation.

Main outcome variables
1-Depression Indicators 2- Anxiety 3-Pain 4-Fear of Movement 5-Fear of Re-Injury

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251121068065N4**
Registration date: **2026-06-10, 1405/03/20**
Registration timing: **prospective**

Last update: **2026-06-10, 1405/03/20**
Update count: **0**

Registration date
2026-06-10, 1405/03/20

Registrant information

Name
kavoushgaran kavoushgaran

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-01, 1405/04/10

Expected recruitment end date
2026-09-21, 1405/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of relaxation-based virtual reality on the psychological indicators of athletes with knee injuries

Public title
The effect of relaxation-based virtual reality on the psychological indicators of athletes with knee injuries

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Male athletes aged 24–34 years. History of anterior cruciate ligament (ACL) reconstruction surgery. History of regular exercise participation during the previous three years. Being in the early phase of postoperative rehabilitation. Referral to the selected physiotherapy clinic and willingness to participate throughout the study.

Exclusion criteria:
Age outside the specified range. Presence of concurrent musculoskeletal injuries other than ACL-related injuries. History of severe psychological disorders before injury. Failure to adhere to the prescribed intervention program. bsence from intervention or assessment sessions.

Age
From **24 years** old to **34 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be enrolled through convenience sampling and subsequently allocated to the intervention group (physiotherapy plus virtual reality–based relaxation) or the control group (physiotherapy alone) using simple randomization. The randomization sequence will be generated using a randomization program based on the research website https://www.randomizer.org. Group allocation will be performed according to the generated sequence to ensure equal probability of allocation for all participants.

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
Research Ethics Committee of University of Mazandaran

Street address
University of Mazandaran, Pasdaran Street, Babolsar, Mazandaran Province, Iran.

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Postal code
47416-13534

Approval date
2024-12-28, 1403/10/08

Ethics committee reference number
IR.UMZ.REC.1403.094

Health conditions studied

1

Description of health condition studied
Anterior Cruciate Ligament (ACL) Injury Following Reconstruction Surgery

ICD-10 code
S83.5

ICD-10 code description
Sprain and strain of cruciate ligament of knee (Anterior Cruciate Ligament injury)

Primary outcomes

1

Description
Anxiety and depression

Timepoint
Depression and anxiety will be assessed at two time points: baseline (pre-test, before the intervention) and immediately after completion of the intervention period (post-test).

Method of measurement
Anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale (HADS). This is a 14-item self-report questionnaire with two subscales measuring anxiety (7 items) and depression (7 items). Each item is scored on a 4-point Likert scale (0–3), with higher scores indicating greater symptom severity. A total score above 11 is considered clinically significant. The validated Persian version of the HADS will be used in this study.

2

Description
Pain intensity

Timepoint

Pain intensity will be assessed at two time points: baseline (pre-test, before the intervention) and immediately after completion of the intervention period (post-test).

Method of measurement

Pain will be assessed using the McGill Pain Questionnaire (MPQ), a validated multidimensional self-report instrument designed to evaluate the sensory and affective dimensions of pain perception. The questionnaire consists of 20 items covering different aspects of pain experience, including sensory qualities (items 1–10), affective/emotional responses (items 11–15), evaluative aspects (item 16), and miscellaneous pain descriptors (items 17–20). Responses are recorded using a structured rating format, and higher scores indicate greater pain intensity and affective distress.

3

Description

Fear of movement (Kinesiophobia)

Timepoint

Fear of movement will be assessed at two time points: baseline (pre-test, before the intervention) and immediately after completion of the intervention period (post-test).

Method of measurement

Fear of movement will be assessed using the Tampa Scale for Kinesiophobia (TSK-11), an 11-item validated self-report questionnaire designed to measure fear of movement and (re)injury-related avoidance beliefs. The scale includes two subdomains: fear of injury (items 1–6) and activity avoidance (items 7–11). Each item is rated on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree), with higher scores indicating greater fear of movement. The TSK-11 has demonstrated acceptable psychometric properties, including good internal consistency in previous research.

4

Description

Fear of re-injury

Timepoint

Fear of re-injury will be assessed at two time points:baseline (pre-test, before the intervention) and immediately after completion of the intervention period (post-test).

Method of measurement

Fear of re-injury will be assessed using a validated self-report questionnaire designed to measure fear of re-injury following sports injury, completed by participants.

Secondary outcomes

1

Description

Pain-related avoidance beliefs and cognitive perceptions of pain

Timepoint

Pain-related avoidance beliefs and cognitive perceptions of pain will be measured at two time points: baseline (pre-test, before intervention) and immediately after the end of the intervention period (post-test).

Method of measurement

Pain avoidance beliefs will be assessed using the questionnaire on avoidance beliefs about pain during work and physical activity, a 16-item self-report instrument developed by Asghari Moghadam et al. The questionnaire evaluates four dimensions: belief in pain persistence, self-blame, stability of pain, and unpredictability of pain. Items are completed by participants, and higher scores indicate stronger maladaptive avoidance beliefs.

Intervention groups

1

Description

Control group: Participants will receive routine physiotherapy alone, including electrotherapy, range-of-motion exercises, muscle strengthening, and functional rehabilitation exercises, without virtual reality–based relaxation.

Category

Rehabilitation

2

Description

Intervention group: Participants will receive routine physiotherapy combined with virtual reality–based relaxation. During physiotherapy sessions, participants will use virtual reality glasses to view immersive nature-based relaxation videos designed to promote psychological relaxation. Conventional physiotherapy will include electrotherapy, range-of-motion exercises, muscle strengthening, and functional rehabilitation exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehregan Physiotherapy Clinic

Full name of responsible person

Dr. Rose Foladi

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Mehregan Physiotherapy Clinic, 1st Floor, Shahriar 3 Doctors Building, Farhang Street, Sari, Iran.

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Sponsors / Funding sources

1

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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
University of Mazandaran
Proportion provided by this source
50
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available