Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of proprioceptive exercises using virtual reality on postural stability and functional balance of military personnel with non-specific back pain

Protocol summary

Study aim

Determining the effectiveness of proprioceptive exercises using virtual reality on postural stability, functional balance and quality of life of people with non-specific back pain in military forces.

Design

A clinical trial with a control group with a parallel group randomized with 45 patients

Settings and conduct

After obtaining permission from the university and obtaining written consent from all patients, the number of 45 target clients (with back pain from Baqiyatullah Hospital) in 1402 who have non-specific chronic back pain were selected as available and voluntarily in participate in this study. The subjects are randomly divided into three experimental groups with virtual reality (N=15), the experimental group performing proprioceptive exercises without virtual reality (N=15) and the control group (N=15) will be.

Participants/Inclusion and exclusion criteria

• Criteria for entering the study: Age range between 18-28 years More than 12 weeks have passed since the onset of back pain. The disability criterion of these patients based on the Quebec questionnaire scale (for the purpose of screening) should be above 25. Taking public health Body mass index between 20 and 26 Drug consumption is reported by the doctor and its dosage by the patient • Exclusion criteria: Physiotherapy treatment in the last six months Having back pain of non-mechanical origin Use of aids such as corsets, braces, and belly bands Participation in regular sports activities during the past six months It does not have any kind of surgery, fracture or pathological damage

Intervention groups

There are three experimental groups with virtual reality (N=15) the experimental group performing proprioceptive exercises without virtual reality (N=15) and the control group (N=15).

Main outcome variables

Non-specific back pain-quality of life-virtual reality-postural stability-pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100505003871N3**
Registration date: **2024-10-20, 1403/07/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-20, 1403/07/29**
Update count: **0**

Registration date

2024-10-20, 1403/07/29

Registrant information

Name

Alireza Shamsoddini

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-21, 1403/05/31

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of proprioceptive exercises using virtual reality on postural stability and functional balance of military personnel with non-specific back pain

Public title
Investigating the effect of proprioceptive exercises using virtual reality on postural stability and functional balance of military personnel with non-specific back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range between 18-28 years More than 12 weeks have passed since the onset of back pain. The disability criterion of these patients based on the Quebec questionnaire scale (for the purpose of screening) should be above 25. Taking public health Body mass index between 20 and 26 Drug consumption is reported by the doctor and its dosage by the patient
Exclusion criteria:
Physiotherapy treatment in the last six months Having back pain of non-mechanical origin Use of aids such as corsets, braces, and belly bands Participation in regular sports activities during the past six months Having any surgery, fracture, dislocation and twisting in the spine Having diseases such as osteoporosis, arthritis, cancer, rheumatism, urinary tract infections and pelvic diseases, disc herniation, sciatica pains, inflammatory diseases, malignant tumors, nervous system diseases and spinal cord lesions, etc or Any skeletal abnormalities that affect the research process.
Age
From **18 years** old to **28 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Random block allocation method will be used to select and group the samples. This allocation is done in several steps, first by using the Random Allocation Software A random sequence will be created with blocks of 6. Then, to hide the random allocation, non-transparent sealed envelopes will be used with the random sequence. Based on the sample size of the research, a number of envelopes with aluminum wrappers (in order not to make the content of the envelopes unclear) will be prepared and each of the random sequences created will be recorded on a card and the cards will be placed inside the envelope in order. Maintaining the random sequence, the numbering on the outer surface of the envelopes will be done in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of the participants, one of the envelopes will be opened according to the order in which the eligible participants entered the study, and They will be placed in one of three groups (virtual reality group, proprioception group and control group).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatullah University of Medical Sciences
Street address
Baqiyatallah University of Medical Science ,Sheikh Fazlollah Nouri Expressway, Mollasadra Bridge,District 2 ,Tehran,1455915371,Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2024-06-28, 1403/04/08
Ethics committee reference number
IR.BMSU.BAQ.REC.1403.049

Health conditions studied

1

Description of health condition studied
Non-specific back pain
ICD-10 code
M54.9
ICD-10 code description
Dorsalgia, unspecified

Primary outcomes

1

Description

Non-specific back pain score based on the Quebec questionnaire

Timepoint

قبل از شروع مداخله و بلافاصله بعد از اخرین جلسه درمانی

Method of measurement

Quebec questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group is not based on virtual reality and will receive only 12 sessions and for a duration of 20-30 minutes in each session, common rehabilitation interventions that include strengthening the paravertebral and lumbar extensor muscles and stretching exercises for the paravertebral and lumbar extensor muscles. . Before the intervention of the patients, Biodex tools to measure postural stability, force plate and Y balance test (YBT) to measure dynamic balance and the stork test (Stroke) to measure static balance to check postural control and balance and also from the grading scale Pain will be used to measure patients' pain.

Category

Rehabilitation

2

Description

Before the intervention of the patients, Biodex tools to measure postural stability, force plate and Y balance test (YBT) to measure dynamic balance and the stork test (Stroke) to measure static balance to check postural control and balance and also from the grading scale Pain will be used to measure patients' pain.

Category

Rehabilitation

3

Description

Control group: The control group will only be shown the recorded videos of virtual reality and will be asked to imitate the exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah Hospital

Full name of responsible person

Alireza shamsodini

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Baqiyatallah University of Medical Science ,Sheikh Fazlollah Nouri Expressway, Mollasadra Bridge,District 2 ,Tehran,1455915371,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Alireza shamsodini

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

No financial resources

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person
Alireza shamsodini
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
A part of the data such as the information related to the main outcome or the like can be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions will be available
Under which criteria data/document could be used
Researchers who intend to study in this area
From where data/document is obtainable
To access this data, the responsible author must give an email
What processes are involved for a request to access data/document
After completing the research, they can email the responsible author to receive the data
Comments