

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Iran (Islamic Republic of)

Phone

+98 21 8248 3353

Email address

alirezaot@bmsu.ac.ir

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 آخرین 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

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

Phone

+98 990 711 6379

Email

alirezaot@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Alireza shamsodini

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

Phone

+98 21 8755 4551

Email

researchsystem@bmsu.ac.ir

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

Street addressBaqiyatallah University of Medical Science ,Sheikh
Fazlollah Nouri Expressway, Mollasadra Bridge, District
2 ,Tehran,1455915371,Iran**City**

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 4551

Email

alirezaot@bmsu.ac.ir

Alireza shamsodini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street addressBaqiyatallah University of Medical Science ,Sheikh
Fazlollah Nouri Expressway, Mollasadra Bridge, District
2 ,Tehran,1455915371,Iran**City**

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 4551

Email

alirezaot@bmsu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiatallah University of Medical Sciences

Full name of responsible person

Alioreza shamsodini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street addressBaqiyatallah University of Medical Science ,Sheikh
Fazlollah Nouri Expressway, Mollasadra Bridge, District
2 ,Tehran,1455915371,Iran**City**

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 4551

Email

alirezaot@bmsu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person**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 DictionaryUndecided - 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 obtainableTo 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**