

# 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

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+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

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

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Alireza shamsodini

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**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

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**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 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**