

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effect of proprioceptive neuromuscular facilitation training on physical and psycho-social characteristics of military personnel with sedentary lifestyle with chronic non-specific low back pain; Clinical Trial.

#### Protocol summary

##### Study aim

The effect of proprioceptive neuromuscular facilitation exercises on the physical and psychosocial characteristics of military personnel with a sedentary lifestyle suffering from non-specific chronic back pain; Clinical trial.

##### Design

Clinical trial, with control group, parallel group, single-blinded, randomized, on 38 chronic low back pain patients, random numbers from the website [www.calculatorsoup.com](http://www.calculatorsoup.com) were used for randomization.

##### Settings and conduct

Baqiyatallah Hospital, Tehran, Iran. First, about 15 minutes of common motor control exercises will be given to both groups, after the motor control exercises, only group A will be given PNF exercise instructions. Each exercise consists of a starting position and an ending position, which will be done as a back and forth movement and lasts about 15 to 20 minutes. In general, each session will be about 45 minutes, total sessions will include 16 sessions. Assessor will be blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-specific chronic back pain; Maximum pain intensity 30 to 60 in the last 24 hours based on the numerical pain scoring scale; Age between 18 and 50 years; Participant's ability to learn and perform exercises; Reading and writing literacy to complete the questionnaires; Sensory and motor health of upper and lower limbs. Exclusion criteria: Prohibition of performing therapeutic exercises for the patient (such as advanced heart and respiratory diseases); The existence of clear deformity in the spine, pelvis and lower limbs; existence of autoimmune diseases.

##### Intervention groups

The control group includes common motor control exercises that are used for low back pain patients. In addition to performing motor control exercises, the

intervention group will also perform diagonal PNF exercises.

##### Main outcome variables

Pain; disability; pain catastrophizing; stress; anxiety; depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200418047120N2**

Registration date: **2023-09-07, 1402/06/16**

Registration timing: **prospective**

Last update: **2023-09-07, 1402/06/16**

Update count: **0**

##### Registration date

2023-09-07, 1402/06/16

##### Registrant information

##### Name

Hamid Zamani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8755 4408

##### Email address

zamani.pt@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-22, 1402/06/31

##### Expected recruitment end date

2024-01-19, 1402/10/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of proprioceptive neuromuscular facilitation training on physical and psycho-social characteristics of military personnel with sedentary lifestyle with chronic non-specific low back pain; Clinical Trial.

**Public title**

Effect of proprioceptive neuromuscular facilitation training on chronic non-specific low back pain.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Non-specific chronic low back pain. Maximum pain intensity between 30 to 60 in last 24 hours according to Numerical Pain Rating Scale. Participants ability to learning and doing the exercises. Reading and writing literacy to complete the questionnaires. Sensory and motor health of upper and lower limbs.

**Exclusion criteria:**

prohibition of performing therapeutic exercises for the patient (such as advanced heart and respiratory diseases); existence of clear deformity in the spine, pelvis and lower limbs; existence of autoimmune diseases (such as rheumatic diseases).

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **38**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization of the samples will be done using the variable block method. In this way, the letter A was determined for the intervention group (including motor control exercises + PNF diagonal exercises) and the letter B was determined for the control group (including motor control exercises). Then 4 non-repeating sequences of letters A and B were determined as follows: 1. AABB 2. BBAA 3. ABAB 4. BABA 5. ABBA 6. BAAB After determining the variable 4-letter blocks, considering that 38 people will be needed, 10 random numbers were extracted from the website (<https://www.calculatorsoup.com/>) (1 5 6 3 2 3 6 4 2 3). In this way, the placement of the participants in the desired groups was determined.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, the evaluation including scoring and data extraction of the questionnaires will be done by someone other than the main researcher of the study who will provide the interventions to the patients.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Baqiyatallah Hospital

**Street address**

Sports Physiology Research Institute, Baqiyatullah University of Medical Sciences, South Sheikh Bahai St., Molla Sadra St.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Approval date**

2023-08-13, 1402/05/22

**Ethics committee reference number**

IR.BMSU.BAQ.REC.1402.055

**Health conditions studied****1****Description of health condition studied**

Non-specific chronic low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Pain intensity

**Timepoint**

At the baseline and after the end of the interventions

**Method of measurement**

Numerical Pain Rating Scale

**Secondary outcomes**

## 1

### **Description**

Disability

### **Timepoint**

At the baseline and after the last intervention session

### **Method of measurement**

Roland-Morris Disability Questionnaire

## 2

### **Description**

Pain Catastrophizing

### **Timepoint**

At the baseline and after the last intervention session

### **Method of measurement**

Pain Catastrophizing Scale

## 3

### **Description**

Depression

### **Timepoint**

At the baseline and after the last intervention session

### **Method of measurement**

Depression-Anxiety and Stress Scale

## 4

### **Description**

Anxiety

### **Timepoint**

At the baseline and after the last intervention session

### **Method of measurement**

Depression-Anxiety and Stress Scale

## 5

### **Description**

Stress

### **Timepoint**

At the baseline and after the last intervention session

### **Method of measurement**

Depression-Anxiety and Stress Scale

## **Intervention groups**

## 1

### **Description**

Intervention group: 16 sessions of Diagonal exercises of proprioceptive neuromuscular facilitation training (PNF) for trunk, 3 weekly sessions, each session 15 to 20 minutes.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: 16 sessions of common motor control exercises of low back pain, 3 weekly sessions, each session 15 to 20 minutes.

## **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Baqiyatullah University of Medical Sciences

#### **Full name of responsible person**

Alireza Shamsoddini

#### **Street address**

Baqiyatullah University of Medical Sciences, South Sheikh Bahai St., Molla Sadra St., Vanek Square, Tehran

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#### **Email**

eprc.webinar@gmail.com

#### **Web page address**

<https://research.bmsu.ac.ir/portal/home/?239518/%D9%85%D8%B1%DA%A9%D8%B2-%D8%AA%D8%AD%D9%82%DB%8C%D9%82%D8%A7%D8%AA-%D9%81%DB%8C%D8%B2%DB%8C%D9%88%D9%84%D9%88%DA%98%DB%8C-%D9%88%D8%B1%D8%B2%D8%B4>

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Bagheiat-allah University of Medical Sciences

#### **Full name of responsible person**

Alireza Shamsoddini

#### **Street address**

Baqiyatullah University of Medical Sciences, South Sheikh Bahai St., Molla Sadra St., Vanak Square, Tehran

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1435916471

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+98 21 8804 0060

#### **Email**

eprc.webinar@gmail.com

#### **Web page address**

<https://www.bmsu.ac.ir/portal/home/>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

**Title of funding source**

Bagheiat-allah University of Medical Sciences

**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**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Alireza Shamsoddini

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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

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**Position**

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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**

Alireza Shamsoddini

**Position**

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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**

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**

Results from the analysis of participant data, both

primary and secondary outcomes, will be published.

**When the data will become available and for how long**

Access to the data will be possible after the publication of the article.

**To whom data/document is available**

Researchers of academic and scientific centers could access the data.

**Under which criteria data/document could be used**

Analyzes that do not overlap with the objectives of the

present study will be allowed.

**From where data/document is obtainable**

Dr. Alireza Shamsoddini Email:  
shamseddin23@gmail.com

**What processes are involved for a request to access data/document**

The requester could access the data by providing the research area as well as the purpose of accessing the data.

**Comments**