

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of proprioceptive exercises on pain, balance and risk of falling in the military elderly with knee osteoarthritis; A Randomized Clinical Trial

#### Protocol summary

##### Study aim

The purpose of study is to investigate of the effect of proprioceptive exercises on pain, balance and risk of falling in the military elderly with knee osteoarthritis

##### Design

Randomized, controlled, single blinded trial

##### Settings and conduct

The study involves 60 elderly military with knee osteoarthritis at Baqiyatullah University of Medical Sciences. After randomization, patients are placed in one of two intervention or control groups. According to previous studies, a handbook will be used to teach traditional exercise programs of physiotherapy to knee osteoarthritis patients. In the intervention group will be taught a protocol of proprioceptive exercises. All exercises will be performed and taught under the supervision of a physiotherapist. Participants will perform these exercises three times a day for 15 repetitions each for six weeks, followed by two weeks of follow-up.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Military seniors in the age group of 55 to 75 years. 2- Patients with unilateral or bilateral knee osteoarthritis based on clinical and radiological examination. 3- Patients who present for more than 3 months with symptoms such as pain, joint stiffness, functional disability, decreased muscle strength, and limitations in daily activities. 4- Numerical pain rating scale (VAS) between 1 and 5. 5- Kellgren and Lawrence grading scale (K/L) 2 and 3 Exclusion criteria: 1- Patients with a history of or undergoing treatment with any intra-articular injection into the knee joint. 2- Muscle strength of the lower limb is less than grade 3. 3- People's unwillingness to continue testing.

##### Intervention groups

There are two groups (Intervention group: proprioceptive exercises with conventional therapeutic exercises, and Control group: Only conventional therapeutic exercises)

#### Main outcome variables

1-pain intensity. 2-risk of falling. 3-balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190322043099N1**

Registration date: **2023-03-09, 1401/12/18**

Registration timing: **prospective**

Last update: **2023-03-09, 1401/12/18**

Update count: **0**

##### Registration date

2023-03-09, 1401/12/18

##### Registrant information

##### Name

Arsalan Ghorbanpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 3939

##### Email address

ghorbanpoura@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-09, 1402/01/20

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of proprioceptive exercises on pain, balance and risk of falling in the military elderly with knee osteoarthritis; A Randomized Clinical Trial

**Public title**  
The effect of proprioceptive exercises in the military elderly with knee osteoarthritis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Military seniors in the age group of 55 to 75 years. Having a body mass index (BMI) between 25 and 30. Patients with unilateral or bilateral knee osteoarthritis based on clinical and radiological examination. Having a doctor's prescription stating that the rehabilitation intervention is suitable and potentially useful. Patients who present for more than 3 months with symptoms such as pain, joint stiffness, functional disability, decreased muscle strength, and limitations in daily activities. Numerical pain rating scale between 1 and 5. Kallgren and Lawrence grading scale (K/L) 2 and 3.  
**Exclusion criteria:**  
Presence of rheumatoid arthritis, polyarthritis, or systemic inflammatory arthritis. Patients with mental defects or taking psychoactive drugs that disrupt the balance. Patients with neurological diseases (stroke, cognitive disorders, cerebellar problems, peripheral vascular conditions, and cerebrovascular diseases). Presence of any ear disorder (especially vertigo or vestibular disorder) affecting balance. Patients with a history of knee, hip, or ankle surgery. Patients with a history of or undergoing treatment with any intra-articular injection into the knee joint. Muscle strength of the lower limb is less than grade 3. People's unwillingness to continue testing.

**Age**  
From **55 years** old to **75 years** old

**Gender**  
Male

**Phase**  
3

**Groups that have been masked**  

- Investigator

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients were randomly divided into three groups by closed envelope method. The allocation of the subjects will be concealed by using sequentially numbered, sealed and opaque envelopes. On the first day of treatment, the envelope allocated will be opened by participant.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**  
Assessor Blind: Data safety will be ensured by assigning Specific Identity numbers and all consent, readings forms will be placed in locker to bind Assessors

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

##### Street address

MollaSadra street , Vanak Square , Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1435916471

#### Approval date

2023-01-09, 1401/10/19

#### Ethics committee reference number

IR.BMSU.BAQ.REC.1401.094

## Health conditions studied

### 1

#### Description of health condition studied

Knee Osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Pain intensity

#### Timepoint

before intervention, after six weeks, and after two weeks follow up

#### Method of measurement

Visual Analogue Scale (VAS)

### 2

#### Description

Risk of falling

### Timepoint

before intervention, after six weeks, and after two weeks follow up

### Method of measurement

Self-efficacy questionnaire of fear of falling among the elderly

## 3

### Description

Balance

### Timepoint

before intervention, after six weeks, and after two weeks follow up

### Method of measurement

1- Berg Balance Scale. 2- Timed Up and Go test.

## Secondary outcomes

## 1

### Description

Disability index

### Timepoint

before intervention, after six weeks, and after two weeks follow up

### Method of measurement

Knee injury and Osteoarthritis Outcome Score; KOOS

## 2

### Description

The level of quality of life of military seniors

### Timepoint

before intervention, after six weeks, and after two weeks follow up

### Method of measurement

36-Item Short Form Survey (SF-36)

## Intervention groups

## 1

### Description

Intervention group: proprioceptive exercises with conventional therapeutic exercises. Proprioceptive Exercises: 1- One-Leg Balance, 2- Toe Walking, 3- Heel Walking, 4- Blind Advanced One-Leg Balance

### Category

Rehabilitation

## 2

### Description

Control group: Conventional therapeutic exercises. Conventional therapeutic Exercises: 1- Isometric Quadriceps Exercises, 2- Sitting Knee Extension Exercises, 3- Straight Leg Raise Exercises, 4- Hamstring stretching Exercises, 5- Hip Abduction and Extension Exercises

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Baqiyatallah University of Medical Sciences

#### Full name of responsible person

Vahid Sobhani

#### Street address

MollaSadra street , Vanak Square , Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1435916471

#### Phone

+98 21 8755 4408

#### Email

sobhani518@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

Abbas Ali Imani Fooladi

#### Street address

Baqiyatallah University, Third Floor, Vice-Chancellor for Research and Technology, Sheikh Bahai St, Mulla Sadra St, Vanak Square

#### City

Tehran

#### Province

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#### Postal code

1435916471

#### Phone

+98 21 8755 5250

#### Email

imanifooladi.a@gmail.com

#### 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**

Vahid Sobhani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

MollaSadra street , Vanak Square , Tehran

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Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8755 4408

**Email**

sobhani518@gmail.com

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

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Vahid Sobhani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

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

Tehran University of Medical Sciences

**Full name of responsible person**

Arsalan Ghorbanpour

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

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Tehran

**Province**

Tehran

**Postal code**

1148965111

**Phone**

+98 21 7753 6586

**Email**

ghorbanoura@razi.tums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

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

**Statistical Analysis Plan**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

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