

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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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

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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

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

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PhD candidate

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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