Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity

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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

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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
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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