

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of two methods using elastic band and flamingo exercise on functional balance, proprioceptive and osteoarthritis indicators in patients with knee osteoarthritis

#### Protocol summary

##### Study aim

Determining the effect of two methods using elastic band and flamingo exercise on functional balance, proprioceptive and osteoarthritis indicators in patients with knee osteoarthritis

##### Design

In this single blind study, 90 people will be randomly divided into three groups: elastic band exercises group, flamingo exercises group and control group.

##### Settings and conduct

90 patients referred to Bu Ali Medical Clinic in Birjand were selected and randomly assigned to three groups: the first group of elastic band exercises program Based on the guidelines of the American School of Sports Medicine, and the second group of They will use the Flamingo movement exercises program for 8 weeks and the third group will continue their daily life. single blind: Participants will be unaware of the intervention groups and the type of interventions in other groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 45 years and older, Diagnosis and confirmation of knee osteoarthritis by a specialist in rheumatology, Kellgren/Lawrence scale knee osteoarthritis grade 2/3, Ability to understand and accept written and informed consent, Ability to walk with or without aids, Do not use a wheelchair to move, No history of surgery and arthroplasty of the knee joint, No Parkinson's disease, epilepsy, dizziness and a history of knee fractures, No underlying diseases such as diabetes, hypothyroidism and neuropathy, Absence of dementia and Alzheimer's, BMI less than 30; Exclusion criteria: Inability to perform movements due to severe pain or orthopedic limitations, Participate in regular exercise or other specific activity

##### Intervention groups

There are 3 groups, 1- Uses elastic bands to perform exercises, 2- Performs flamingo exercises and 3- the

control group does not perform any of the above interventions.

##### Main outcome variables

Changes in functional balance score, proprioceptive and osteoarthritis indices

#### General information

##### Reason for update

Record the date of the patient

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200807048331N1**

Registration date: **2020-08-31, 1399/06/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-06, 1399/11/18**

Update count: **1**

##### Registration date

2020-08-31, 1399/06/10

##### Registrant information

###### Name

Ali Sheikhalishahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3722 0539

###### Email address

ali.sheikhalishahi@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-31, 1399/06/10

##### Expected recruitment end date

2020-12-20, 1399/09/30  
**Actual recruitment start date**  
2020-08-31, 1399/06/10  
**Actual recruitment end date**  
2020-10-31, 1399/08/10  
**Trial completion date**  
2021-01-06, 1399/10/17

#### Scientific title

Comparison of the effect of two methods using elastic band and flamingo exercise on functional balance, proprioceptive and osteoarthritis indicators in patients with knee osteoarthritis

#### Public title

Comparison of the effect of using elastic band and flamingo exercise on knee osteoarthritis

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

45 years and older Diagnosis and confirmation of knee osteoarthritis by a specialist in rheumatology Kellgren/Lawrence scale knee osteoarthritis grade 2 and 3 Ability to understand and accept written and informed consent Ability to walk with or without aids Do not use a wheelchair to move No history of surgery and arthroplasty of the knee joint No Parkinson's disease, epilepsy, dizziness and a history of knee fractures No underlying diseases such as diabetes, hypothyroidism and neuropathy Absence of dementia and Alzheimer's BMI less than 30

##### Exclusion criteria:

Inability to perform movements due to severe pain or orthopedic limitations Participate in regular exercise or other specific activity

#### Age

From **45 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **90**

Actual sample size reached: **82**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization of individuals in the form of restricted randomization will be of the type of random allocation rule. In this way, cards are prepared according to the number of participants and the names of the intervention methods are written on them and placed in a box. Individuals are asked to randomly remove a card from the box (selected cards will not be returned to the box after selection). In this way, the type of intervention will be determined for each person and random allocation will be performed.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

This study will be of the single blind type. In this way, participants will be unaware of the intervention groups and the type of interventions in other groups and will only perform the intervention intended for them by entering one of the groups.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

##### Street address

Deputy of research and technology, Birjand University of Medical Sciences, Ghafari Street

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717853577

#### Approval date

2020-07-13, 1399/04/23

#### Ethics committee reference number

IR.BUMS.REC.1399.165

## 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

Functional balance

#### Timepoint

Before the intervention and after the end of the intervention

#### Method of measurement

Berg balance scale, Timed up and go test

## 2

### **Description**

Proprioceptive

### **Timepoint**

Before the intervention and after the end of the intervention

### **Method of measurement**

Active movement extent discrimination apparatus

## 3

### **Description**

Pain

### **Timepoint**

Before the intervention and after the end of the intervention

### **Method of measurement**

Western Ontario and McMaster universities osteoarthritis index, Visual analogue scale

## 4

### **Description**

Joint stiffness

### **Timepoint**

Before the intervention and after the end of the intervention

### **Method of measurement**

Western Ontario and McMaster universities osteoarthritis index

## 5

### **Description**

Physical performance

### **Timepoint**

Before the intervention and after the end of the intervention

### **Method of measurement**

Western Ontario and McMaster universities osteoarthritis index

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Intervention group 1: Elastic band exercise group that continues these exercises for 8 weeks. The training program for the elastic band will be based on the guidelines provided by the American School of Sports Medicine. This program will include 5-10 minutes of warm-up before training, 5-10 minutes of cooling down after training and 5 sets with 10 repetitions, three days a week for up to 8 weeks and at certain hours (evening). In the first four weeks, a low-strength elastic band (yellow) is used. To increase the resistance of the exercises in the following weeks, by

adding one more repetition to the previous movements, up to 15 repetitions and replacement with a new band (red color) will continue. Exercises in this group will include knee flexion / extension, ankle dorsiflexion / plantarflexion, hip adduction / abduction, hip flexion / extension, and internal /external rotation hip.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: The second intervention group is the flamingo exercise group. The training program of this group includes standing on one leg, three times a day, each time for one minute and eight weeks and at certain hours (evening). While doing this exercise, the eyes are open and the hand raised to the upper leg may be leaning somewhere and the other hand may be freely in line with the body.

#### **Category**

Rehabilitation

### 3

#### **Description**

Control group: Group 3: They do not receive any of the above exercises and lead a normal life.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Bouali Birjand Medical Clinic

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

Elham Atabati

##### **Street address**

18 Ghafari Alley, Ghafari street

##### **City**

Birjand

##### **Province**

South Khorasan

##### **Postal code**

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##### **Phone**

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##### **Email**

elham1405@yahoo.com

##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Birjand University of Medical Sciences

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

Tooba Kazemi

**Street address**

Birjand University of Medical Sciences, Ghafari Street

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**Email**

drtooba.kazemi@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Ali Sheikhalishahi

**Position**

M.Sc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

19 Edalat Alley, Edalat street, Azadshahr

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Mohsen Foadoddini

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Ali Sheikhalishahi

**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Edalat 19 Alley, Edalat St, Azadshahr

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**Postal code**

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**Phone**

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**Fax**

**Email**

alishikhalishahi95@gmail.com

**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**  
Not applicable  
**Title and more details about the data/document**  
Information on the main outcome will be available  
**When the data will become available and for how long**

Access starts 6 months after the results are published  
**To whom data/document is available**  
Researchers  
**Under which criteria data/document could be used**  
.  
**From where data/document is obtainable**  
alishkhalishahi95@gmail.com  
ali.sheikhalishahi@bums.ac.ir  
**What processes are involved for a request to access data/document**  
.  
**Comments**