Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person

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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
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

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Person responsible for scientific inquiries

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Mohsen Foadoddini

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Associate professor

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Person responsible for updating data

Contact

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Position
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Latest degree
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Other areas of specialty/work
Nursery

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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

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From where data/document is obtainable

alisheikhalishahi95@gmail.com

ali.sheikhalishahi@bums.ac.ir

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

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Comments