

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effects of a home-based exercise intervention on women with knee osteoarthritis

Protocol summary

Study aim

The aim of this study is to determine the effect of eight weeks of selected exercises at home on women with knee osteoarthritis.

Design

Single-blind randomized clinical trial with control group (n=34).

Settings and conduct

The present quasi-experimental study is performed in the rehabilitation laboratory of Arak University. The experimental group perform home-based exercise for 8 weeks, 3 sessions per week. Knee Injury and Osteoarthritis Outcome Score Western Ontario and McMaster Universities Arthritis Index Static and dynamic balance, quality of life, fear of falling, physical and cognitive self-efficacy measure with 4 stage static balance test, timed up and go test, OPQOL-35, FES-I questionnaire, SSEA and MMSE questionnaire respectively. Data analyzer and evaluators do not know how to allocate and group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of orthopedic specialist that she has osteoarthritis, age 45 to 60 years, knee pain for at least three months, being at the functional level II and III Exclusion criteria: History of knee surgery, Body mass index more than 30, Any illness that can affect the research variables.

Intervention groups

Intervention group: Participants in the intervention group perform selected exercises for eight weeks, three sessions per week. Control group: The control group will have the usual routine of their lives.

Main outcome variables

Range of motion of joint Q angle Pain Quality of life Performance Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046368N8**

Registration date: **2021-11-18, 1400/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-18, 1400/08/27**

Update count: **0**

Registration date

2021-11-18, 1400/08/27

Registrant information

Name

Zahra Raeisi

Name of organization / entity

Arak University

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3492

Email address

z_raisi13@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-18, 1400/08/27

Expected recruitment end date

2021-11-24, 1400/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of a home-based exercise intervention on women with knee osteoarthritis

Public title

The home-based exercise intervention and women with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmation of orthopedic specialist that she has osteoarthritis Age 45 to 60 years Knee pain for at least three months Being at the functional level II and III

Exclusion criteria:

History of knee surgery Body mass index more than 30 Any illness that can affect the research variables

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is parallel. The randomization unit is individual. The Rand List software is used to randomly assign subjects to study groups. At , the number of subjects and groups is given to the software. Then, with this software, each subject is assigned a code. A group is then randomly assigned to each code by the software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer will not be aware of the groups classification. The information of the groups will be provided to the data analyzer in the form of numbers 1, 2, 3 and for each participant with a code.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Arak University of Medical Sciences

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Shahid Shiroodi Street

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3819693345

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.ARAKMU.REC.1400.185

Health conditions studied**1****Description of health condition studied**

osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Pain

Timepoint

Before and after of intervention

Method of measurement

Visual analogue scale

2**Description**

Quality of life

Timepoint

Before and after intervention

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS)

3**Description**

Knee range of motion

Timepoint

Before and after intervention

Method of measurement

Goniometer

Secondary outcomes**1****Description**

Q angle

Timepoint

Before and after intervention

Method of measurement

Goniometer

2

Description

Range of motion of hip joint

Timepoint

Before and after intervention

Method of measurement

Goniometer

3

Description

Static balance

Timepoint

Before and after intervention

Method of measurement

Single leg stance

4

Description

Dynamic balance

Timepoint

Before and after intervention

Method of measurement

Time up and go test

5

Description

Performance

Timepoint

Before and after intervention

Method of measurement

Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Intervention groups

1

Description

Intervention group: The intervention group performs selected home-based exercises for 8 weeks, 3 sessions per week. Subjects are monitored by researchers every week. They write down their activity level in a notebook. Exercise booklet including complete guide and video including explanations and how to perform the exercises correctly will be provided to the participants.

Category

Rehabilitation

2

Description

Control group: The control group performs their normal activities for 8 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak university

Full name of responsible person

Zahra Raeisi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Arak university

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

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable