

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the effectiveness of a home-based exercise program via the mobile application (Varzeshyar) and a routine home-based exercise program on pain and disability of knee osteoarthritis in patients at ages older than 55

#### Protocol summary

##### Study aim

Mobile application development with animation learning exercise training Effectiveness of a home-based exercise program via the mobile application on pain and disability of knee osteoarthritis

##### Design

Required application will be developed at first then 100 patients older than 55 years with knee osteoarthritis will be selected and based on computer randomization put in 2 groups: intervention and control. Intervention group will receive application on their phones and control group from pamphlet.

##### Settings and conduct

The patients with knee osteoarthritis who referred to clinic of rheumatology in Rasoole Akram hospital from 3 March 2018 to 22 October 2018 will be examined. after take demographic information they will be divided in 2 groups: intervention and control. exercise protocol contains 10 movement for lower limb(strengthening and stretching). According to allowed movements for each person a home-based exercise training will be developed and progressively will complete in 4 weeks and will continue for 8 weeks for maintenance therapy.

##### Participants/Inclusion and exclusion criteria

Entry: The patients who suffer from primary knee osteoarthritis that according to Kellgren and Lawrence classification have grade 2 to 4 severity of disease and have osteoarthritis based on A.C.R criteria No entry: Inability to use of mobile application and smart phone Limitation in strengthening exercise Age less than 50 years

##### Intervention groups

Home\_ based exercise with mobile application: The impact of home based exercise with mobile application on pain, disability and quality of life in patients with knee osteoarthritis. Home\_ based exercise with pamphlet: The

impact of home based exercise with pamphlet on pain, disability and quality of life in patients with knee osteoarthritis.

##### Main outcome variables

pain; Quality of life ; Disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190116042386N1**

Registration date: **2019-02-12, 1397/11/23**

Registration timing: **retrospective**

Last update: **2019-02-12, 1397/11/23**

Update count: **0**

##### Registration date

2019-02-12, 1397/11/23

##### Registrant information

##### Name

Zohre Abbaszade

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6657 4251

##### Email address

kianmehr.n@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-03, 1396/12/12

**Expected recruitment end date**

2018-10-04, 1397/07/12

**Actual recruitment start date**

2018-03-03, 1396/12/12

**Actual recruitment end date**

2018-10-22, 1397/07/30

**Trial completion date**

2019-01-20, 1397/10/30

**Scientific title**

Comparing the effectiveness of a home-based exercise program via the mobile application (Varzeshyar) and a routine home-based exercise program on pain and disability of knee osteoarthritis in patients at ages older than 55

**Public title**

Effectiveness of a home-based exercise program via the mobile application (Varzeshyar) on pain and disability of knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients who suffer from primary knee osteoarthritis that according to Kellgren and Lawrence classification have grade 2 to 4 severity of disease and have osteoarthritis based on ACR criteria

**Exclusion criteria:**

Age less than 50 years  
Limitation in strengthening exercise  
Inability to use of mobile application and smart phone

**Age**

From **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

Actual sample size reached: **135**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Computer randomization based on file number

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

No. 270-3, Golshan Ave., Jomhoury Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1313634519

**Approval date**

2017-11-28, 1396/09/07

**Ethics committee reference number**

IR.IUMS.FMD.REC 1396.9411497003/

**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**

Disability score in WOMAC questionnaire

**Timepoint**

WOMAC questionnaire score at start of study, week 4, week 12

**Method of measurement**

WOMAC questionnaire

**2****Description**

Symptoms severity score in Lequesne questionnaire

**Timepoint**

Lequesne questionnaire score at start of study, week 4, week 12

**Method of measurement**

Lequesne questionnaire

**3****Description**

Quality of life score in SF8 questionnaire

**Timepoint**

SF8 questionnaire score at start of study, week 4, week 12

**Method of measurement**

SF8 questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Home\_ based exercise training with mobile application

### Category

Treatment - Other

2

### Description

Control group: Home\_ based exercise training with pamphlet

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Rasoole Akram hospital

#### Full name of responsible person

Dr Nahid Kianmehr

#### Street address

Rasoole Akram hospital, Maziyare Mansoori Ave,  
Sattarkhan

#### City

Tehran

#### Province

Tehran

#### Postal code

1445613131

#### Phone

+98 21 6651 5009

#### Email

Kianmehr.n@iums.ac.ir

#### Web page address

http://iums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr Kazem Malakooti

#### Street address

Rasoole Akram hospital, Maziyare Mansoori Ave,  
Sattarkhan

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#### Web page address

http://iums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Zohre Abbaszade

#### Position

Medical resident

#### Latest degree

Specialist

#### Other areas of specialty/work

Geriatrics

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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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 additional information.

### 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Study protocol: The entire study protocol is shareable.

Statistical Analysis Map: The entire statistical analysis

map is shareable. clinical study report: The entire clinical

study report is shareable. Data categorization system:

The Data categorization system is shareable.

### When the data will become available and for how long

Start the access period 2 months after printing results

### To whom data/document is available

Researchers working in Academic Institutions

### Under which criteria data/document could be used

For any kind of research in the field of medicine is possible.

### From where data/document is obtainable

Dr Zohre Abbaszade 09132383725

zanasim88@gmail.com

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

After sending the request by email within 2 weeks, the documentation is sent by email.

### Comments