

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of effectiveness of an etiologic-based exercise and conventional exercises on knee loading, pain and functional activity in individuals with Knee osteoarthritis: A randomized clinical trials.

#### Protocol summary

##### Study aim

This study is designed to compare the effectiveness of a reduction knee adduction moment exercise (etiologic-based exercise) and conventional exercises on biomechanical and clinical measures in individuals with Knee osteoarthritis.

##### Design

This study was a randomized, double-blind, parallel-design clinical trial.

##### Settings and conduct

This study compares three methods of exercise therapy in patients with knee osteoarthritis. Patients at Djavad Mowafaghian research center of intelligent neuro-rehabilitation technologies are treated for one month with one of the exercise methods. All measurements will be performed by a blind assessor to the groups of study before and after intervention and one month after intervention. Patients and data analysts were also blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included having mild to moderate chronic osteoarthritis of tibiofemoral joint and 45-76 years old. Reporting other diseases and use of invasive treatments in the lower extremities consider as exclusion criteria.

##### Intervention groups

1. Intervention group 1: treated by education, ultrasound therapy, hot pack, electrostimulator (TENS) and yoga exercise and medial thrust gait training For 4 weeks and 3 sessions per week 2. Intervention group 2: treated by education, ultrasound therapy, hot pack, TENS and quadriceps and hamstring strength training For 4 weeks and 3 sessions per week 3. Intervention group 3: treated by education, ultrasound therapy, hot pack, TENS and walking exercise For 4 weeks and 3 sessions per week

##### Main outcome variables

Anterior knee pain; functional activity during gait; knee joint loading during gait.

#### General information

##### Reason for update

Adding a new treatment group; Following the publication of the study protocol, experts suggested that a new treatment group with only normal walking exercise be added to the study to ensure control of the results of the study.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201702222793N4**

Registration date: **2017-06-27, 1396/04/06**

Registration timing: **prospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **1**

##### Registration date

2017-06-27, 1396/04/06

##### Registrant information

##### Name

Shahla Zahednejad

##### Name of organization / entity

School Of Rehabilitation Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3102

##### Email address

snejad@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-12-22, 1396/10/01  
**Actual recruitment start date**  
2017-07-23, 1396/05/01  
**Actual recruitment end date**  
2018-09-11, 1397/06/20  
**Trial completion date**  
2018-10-12, 1397/07/20

### Scientific title

Comparison of effectiveness of an etiologic-based exercise and conventional exercises on knee loading, pain and functional activity in individuals with Knee osteoarthritis: A randomized clinical trials.

### Public title

Comparison of an etiologic-based exercise and conventional exercises on knee loading in individuals with Knee osteoarthritis.

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

having mild to moderate chronic osteoarthritis of unilaterally or bilaterally tibiofemoral joint according to the method of Kellgren and Lawrance 45-76 years old a history of symptoms more than a month being able to walk without assistant devices having the recent anterior and lateral x-ray image of knee

#### Exclusion criteria:

Reporting other diseases such as: diabetes, diseases of musculoskeletal, neuromuscular and uncontrolled diseases of cardiovascular, respiratory and uncontrolled hypertension the use of injections or other invasive treatments (such as surgery) in the lower extremities during the last three months having an artificial hip or knee joints taking painkiller history of trauma to knee joint during last week performing regular professional exercise extreme physical weakness

### Age

From **45 years** old to **76 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Outcome assessor
- Data analyser

### Sample size

Target sample size: **30**

Actual sample size reached: **27**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The volunteers were divided among the treatment groups by using the closed envelopes. The closed were only available to a technician at the research center who was not a part of the research team. After the pre-treatment evaluation, patients were asked to select one envelope from a box containing several envelopes. After opening the envelope, the patient was referred to the therapist based on the patient's group number to begin

treatment. Then the covariate adaptive randomization technique was used for group assignment ensuring a balanced assignment of participants over the covariates of pain severity, the K-L score, age and body mass index.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Results were evaluated by a person who was not involved in the study design. She was only aware of the participants' illnesses and the consequences that need to be measured. So outcome assessor were blinded to the study purpose, number of groups, and treatment differences. She was also unaware of any patient group. The data analyzer was entered into the research group after completing the study. He was blind to all aspects of the study including purpose, groups, and treatments and he identified treatment groups as groups 1, 2 and 3 without recognizing the differences.

### Placebo

Not used

### Assignment

Parallel

### Other design features

Randomization by sealed envelope

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences  
Ethics Committee

##### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Esfand Avenue, Golestan

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

#### Approval date

2017-06-17, 1396/03/27

#### Ethics committee reference number

IR.AJUMS.REC.1396.317

## Health conditions studied

### 1

#### Description of health condition studied

Knee osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Primary gonarthrosis, bilateral

## Primary outcomes

### 1

#### Description

Knee joint loading

#### Timepoint

pre and post treatment and 1 month after treatment

#### Method of measurement

assessment of knee adduction moment by 3D motion analysis and force plate

## Secondary outcomes

### 1

#### Description

functional activity

#### Timepoint

pre and post intervention and one month after intervention

#### Method of measurement

using of 2 minute walking test

### 2

#### Description

pain

#### Timepoint

study pre and post intervention and one month after intervention

#### Method of measurement

using of visual analogue scale and the short WOMAC scale

## Intervention groups

### 1

#### Description

Intervention group 1: Patients treated for 4 weeks and 3 sessions per week by 20 minute electrical stimulation, educational leaflet, 5 minute continuous ultrasound therapy, hot pack and 3 set yoga exercise and 20 minute medial thrust gait training.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: Patients treated for 4 weeks and 3 sessions per week by 20 minute electrical stimulation, educational leaflet, 5 minute continuous ultrasound therapy, hot pack and 3 set quadriceps and hamstring strength training by the resistance flexion and extension knee exercise.

#### Category

Treatment - Other

### 3

#### Description

Intervention group: Patients will be treated for 4 weeks and 3 sessions per week by 20 minute electrical stimulation, educational leaflet, 5 minute continuous ultrasound therapy, hot pack and 20 minute walking exercise on treadmill.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mowafaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies

##### Full name of responsible person

Dr. Farahmand

##### Street address

No 11, Khark Street, Enghelab Street

##### City

Tehran

##### Province

Tehran

##### Postal code

13813-11339

##### Phone

+98 21 6671 6100

##### Email

contact@sharifrehab.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Dr. Makhmalzadeh

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

##### Phone

+98 61 3311 1111

##### Email

info@ajums.ac.ir

##### Grant name

-

##### Grant code / Reference number

-

##### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Zahednejad

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3161

**Fax****Email**

dr.shzahed@gmail.com

**Web page address**

Esfand Avenue, Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3161

**Fax****Email**

dr.shzahed@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Zahednejad

**Position**

faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3161

**Fax****Email**

dr.shzahed@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Zahednejad

**Position**

faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Ahvaz Jundishapur University of Medical Sciences,

**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**

Not applicable

**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**

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

