Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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. Than 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

Khouzestan

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
assesment of knee aduction 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
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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
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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
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
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Position
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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
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

Data Dictionary	Not applicable