

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison the effects of an educational program based on stage of change theory with drug therapy on health related quality of life, pain reduction and disability improvement of patients living with knee osteoarthritis.

Protocol summary

Summary

This controlled clinical trial study was designed to examine the effects of a developed theory based multidisciplinary educational program on quality of life of patients suffering from knee osteoarthritis. This study will be conducted on 146 eligible participants who have key criteria such as being aged > 35 years, having definitive diagnosis of knee osteoarthritis, not suffering from any infection or malignancy on vertebra. This patients will be randomly divided to control or intervention group with 73 patients with each one. Patients in the control group will receive just oral drug treatment while patients in the intervention group will receive oral drug treatment plus multidisciplinary rehabilitation program. The primary outcomes of the study will be quality of life and secondary outcome will be pain and physical function of the patients that will be assessed up to 6- month follow up. Data on three standard scales regarding quality of life, pain and physical function will be collected at 3-, and 6 - month follow ups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102110603N1**

Registration date: **2012-11-07, 1391/08/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-11-07, 1391/08/17

Registrant information

Name

Sedigheh Sadat Tavafian

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4547

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tavafian@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of an educational program based on stage of change theory with drug therapy on health related quality of life, pain reduction and disability improvement of patients living with knee osteoarthritis.

Public title

The effects of designed educational program on health related quality of life of knee osteoarthritis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: aged ≥ 35 years; suffering from knee osteoarthritis for at least 3 months. Exclusion criteria: rheumatoid arthritis or other inflammatory joint disease; serious co-morbidities; having knee surgery within 6 months of commencing the study; having physical impairments that preclude fulfillment of the requirements of either program

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

Ethics Committee of Tehran University of Medical Sciences, Poursina St., Keshavarz Ave, Tehran, Iran.

City

Tehran

Postal code

Approval date

2012-07-31, 1391/05/10

Ethics committee reference number

61553

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis [arthrosis of knee

Primary outcomes

1

Description

quality of life

Timepoint

3 and 6 months after intervention

Method of measurement

The short Form Health Survey (SF- 36)

2

Description

Pain

Timepoint

3 and 6 months after intervention

Method of measurement

Visual Analog Scale (VAS)

3

Description

physical function

Timepoint

3 and 6 months after intervention

Method of measurement

(HAQ) Health Assessment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

There is no intervention for control group. Throughout the study medications such as analgesics, NSAIDs, and antidepressant drugs will be prescribed for participants in control group as necessary.

Category

N/A

2

Description

The intervention in intervention group is a group-based multidisciplinary rehabilitation program which involves relevant specialists to educate for 9 hours . The different specialists would be physiotherapist (1 - hour theory class and 2 - hour practical class), Rheumatologist (1- hour theory class), nutritionist (1- hour theory class), psychologist (2 - hour theory class) and health education specialist (2 - hour theory class).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Research Center of Tehran University of Medical Sciences

Full name of responsible person

Sedigheh Sadat Tavafian

Street address

No 212, Health Education Department, Faculty of Sciences, Tarbiat Modares University, Jalale Ale Ahmad Ave, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rheumatology Research Center of Tehran University of Medical Sciences

Full name of responsible person

Ahmad Reza Jamshidi

Street address

Rheumatology Research Center, Shariati Hosital, Jalale Ale Ahmad Ave, Tehran, Iran.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rheumatology Research Center of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Sedigheh sadat Tavafian

Position

Faculty member/ Associate prof.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty