

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Effectiveness of self care education versus usual care on helplessness and pain in patients with osteoarthritis referring to Tabriz Rheumatological Clinics, 2012: A Randomized Controlled Trial Study

Protocol summary

Summary

Purpose of this double blind randomized controlled trial study is evaluation the effectiveness of self care education on helplessness and pain in patients with osteoarthritis referring to Rheumatology Clinics of Tabriz University of Medical Sciences, Iran. Inclusion criteria of this study included : having knee idiopathic osteoarthritis; having primary education; Living in Tabriz and suburbs and exclusion criteria include: having age below 35 years; participated in similar studies; having history of surgery or Corticosteroid injection on knee joints. After convenience sampling,150 participants will be randomly assigned to two group using Random.org Website. Self care 's demands will determine with individualized interview for intervention group. Intervention stage will be held up at three sessions with one hour time. Educational materials will be distributed in booklet and CD of exercise training to intervention group. Program adherence will be follow with a phone calling twice a week to six weeks. The control group will receive usual treatment and the study materials will be provided for them at the end of study. Data were collected at baseline, six weeks, and 12 weeks. Arthritis Helplessness Index with fifteen items and Visual Analog Scale for pain severity will be used to data collection. Helplessness and pain are primary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106086698N2**

Registration date: **2012-09-28, 1391/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-28, 1391/07/07

Registrant information

Name

Mozhgan Behshid

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

hsr_co@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of self care education versus usual care on helplessness and pain in patients with osteoarthritis referring to Tabriz Rheumatological Clinics, 2012: A Randomized Controlled Trial Study

Public title

Effectiveness of Self Care Education on Helplessness

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria of this study included : having knee idiopathic osteoarthritis; having primary education; Living in Tabriz and suburbs and exclusion criteria include: having age below 35 years; participated in similar studies; having history of surgery or Corticosteroid injection on knee joints.

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Golgasht st.

City
Tabriz

Postal code

Approval date
2012-08-06, 1391/05/16

Ethics committee reference number
4582/4/5

Health conditions studied

1

Description of health condition studied
osteoarthritis

ICD-10 code
M15-M19

ICD-10 code description
Arthrosis

Primary outcomes

1

Description
Helplessness

Timepoint
Before intervention, six weeks and 12weeks after intervention

Method of measurement
Arthritis Helplessness Index

2

Description
pain

Timepoint
before intervention, six weeks and 12 weeks after intervention

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: self care education programs which includes two sessions of disease meaning education , non-pharmacological methods of pain control, nutrition and weight management, joint protection techniques, medication and a session for exercise training. period of these sessions is one hour.

Category
Lifestyle

2

Description
control group: According to the common protocol, routine treatment and training will be received without wane.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sheikh_al_reis clinic

Full name of responsible person
Ali reza Khabazi

Street address

City
Tabriz

2

Recruitment center

Name of recruitment center

Rheumatology Clinic of sina hospital

Full name of responsible person

Ali reza Khabazi

Street address**City**

Tabriz

3

Recruitment center

Name of recruitment center

Gholghasht Clinic

Full name of responsible person

Susan Kolahi

Street address**City**

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

National Public Health Management Center

Street address

Tavanir Exit, Pasdaran Highway

City

Tabriz

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zhaleh Varmaziar

Position

Master of Nursing/ student

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Web page address

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