

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Effectiveness of self help groups versus usual care in quality of life and self efficacy in patients with osteoarthritis referring to Shohada medical center and Sheikhalraees Clinic of Tabriz, 2010:Randomized controlled trial

Protocol summary

Summary

Purpose of this triple blind randomized controlled trial study is evaluation the Effectiveness of self help groups in quality of life and self efficacy in patients with osteoarthritis referring to two Rheumatology and Orthopedic Clinics of Tabriz, Iran. After purposive sampling, 400 participants will be randomly assigned to two groups using Random.org Website. The interviewers, participants and doctors will not be aware of samples allocation. The control group will be received usual care and the intervention group will be used group therapy sessions besides usual care. Purpose of double blind randomized controlled trial study is evaluation the Effectiveness of self help groups in quality of life and self efficacy in patients with osteoarthritis. Having moderate or severe idiopathic osteoarthritis and having vision and hearing impairment and inability to speak are respectively important inclusion and exclusion criteria of this study.. After purposive sampling among patients referring to two Rheumatology and Orthopedic Clinics of Tabriz, Iran, 400 participants will be randomly assigned to two groups using Random.org Website. The interviewers, participants and doctors will not be aware of samples allocation. The control group will be received usual care and the intervention group will be used group therapy sessions besides usual care. Group therapy will be administrated in groups with 8-10 persons for six months which these will be administrated fortnight at first two months and then monthly. At all group therapy sessions, Nurses are responsible for managing and directing the discussions. Depending on the subject, a rheumatologist will participate in group discussions in the right direction as a facilitator. One month after completion of sessions, both intervention and control groups will be filled Quality of life questionnaire and, Arthritis self-efficacy scale of Stanford Patient Education

Research Center with the help of interviewers for the second time. Quality of life and self-efficacy are primary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106036698N1**
Registration date: **2012-01-19, 1390/10/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-19, 1390/10/29

Registrant information

Name

Mozhgan Behshid

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+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

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Effectiveness of self help groups versus usual care in quality of life and self efficacy in patients with osteoarthritis referring to Shohada medical center and Sheikhalraees Clinic of Tabriz, 2010:Randomized controlled trial

Public title
Effectiveness of self help groups in osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: having knee osteoarthritis; able to communicate; Living in Tabriz and suburbs. Exclusion criteria: having mild and traumatic osteoarthritis; having age below 40 and over 60 years; vision and hearing impairment and inability to speak; don't have refractory disease and psychological problems; disability to travel and regular participation in group therapy sessions (intervention group); Following a treatment other than those prescribed; sever osteoarthritis in other joints (except knee).

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **400**

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
golghasht street

City
Tabriz

Postal code

Approval date
2011-01-02, 1389/10/12

Ethics committee reference number
5/4/7952

Health conditions studied

1

Description of health condition studied
Osteoarthritis

ICD-10 code
M17.9

ICD-10 code description
Gonarthrosis, unspecified

Primary outcomes

1

Description
Quality of life

Timepoint
6 month

Method of measurement
SF-36 Quality of life questionnaire

2

Description
self-efficacy

Timepoint
6 month

Method of measurement
Arthritis self-efficacy scale of Stanford Patient Education Research Center

Secondary outcomes

1

Description
pain

Timepoint
6 month

Method of measurement
visual analogue scale

Intervention groups

1

Description
control group: usual care in these patients include pharmacological therapy and training which physician

provides them.

Category

N/A

2

Description

intervention group: Group therapy will be administrated in groups with 8-10 persons for six months which these will be administrated fortnight at first two months and then monthly. After introduction and interaction between members in the initial group session, educational needs to be determined. Then all sessions' themes will be determined and will be provided for intervention group members

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada medical center

Full name of responsible person

Street address

City

Tabriz

2

Recruitment center

Name of recruitment center

Sheikhalraees clinic

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi(Research vice-chancellor)

Street address

Daneshgah st, Moavenate Pajhoheshi

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

Mozhgan Behshid

Position

MS Nursing/Academic staff

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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