

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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)

##### 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

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**

**Street address**

Faculty of Nursing and Midwifery, South Shariaty

**City**

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+98 41 1335 8718

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**Person responsible for updating data**

**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*