

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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

### Other areas of specialty/work

#### Street address

Southern Shariati St.

#### City

Tabriz

#### Postal code

#### Phone

+98 41 1335 8718

#### Fax

#### Email

zhaleh.varmaziar@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Mojgan Behshid

#### Position

Master of Nursing/M.S

#### Other areas of specialty/work

#### Street address

Southern Shariati St.

#### City

Tabriz

#### Postal code

#### Phone

+98 41 1335 8718

#### Fax

#### Email

mojganbehshid@hotmail.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Mojgan Behshid

#### Position

Master of Nursing/M.S

#### Other areas of specialty/work

#### Street address

Southern Shariaty St.

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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*