

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of self care education on disease outcomes in patients with osteoarthritis referring to Rheumatology Clinic of Tabriz University of Medical Sciences 2011: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 disease outcomes in patients with osteoarthritis referring to Rheumatology Clinic of Tabriz, Iran. After convenience sampling, 80 participants will be randomly assigned to two group using Random.org Website. Self care's demands will determine with individualized interview for intervention group. Two intervention sessions include an individualized self care education session and group exercise training session. Educational materials will be distributed in booklet form in intervention group. Program adherence will be follow with a phone calling once a week for 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. Western Ontario and McMaster Universities) WOMAC (questionnaire with five dimensions will used for data collection, that include pain, stiffness, physical function, social function and emotional function. These five dimensions are primary outcomes. Inclusion criteria of this study include age over 35; having primary osteoarthritis and having Primary education, and also exclusion criteria included having other diseases that may effect on pain and physical activity and having history of surgery on joints.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106156810N1**
Registration date: **2011-07-11, 1390/04/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-11, 1390/04/20

Registrant information

Name

Alireza Mohajjel Aghdam

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

mohajjela@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self care education on disease outcomes in patients with osteoarthritis referring to Rheumatology Clinic of Tabriz University of Medical Sciences 2011:A Randomized controlled trial study

Public title

The effect of self care education on disease outcomes in

patients with osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: age over 35; having primary osteoarthritis and having Primary education. Exclusion criteria: having other diseases that may effect on pain and physical activity and having history of surgery on 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: **80**

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
2011-06-22, 1390/04/01

Ethics committee reference number
5/4/2586

Health conditions studied

1

Description of health condition studied
Osteoartheritise

ICD-10 code
M15-M19

ICD-10 code description

arthrosis

Primary outcomes

1

Description
pain

Timepoint
3 month

Method of measurement
womac

2

Description
stiffness

Timepoint
3 month

Method of measurement
womac

3

Description
Physical function

Timepoint
3 month

Method of measurement
womac

4

Description
Social function

Timepoint
3 month

Method of measurement
womac

5

Description
Emotional function

Timepoint
3 month

Method of measurement
womac

Secondary outcomes

1

Description
The amount and frequency of analgesics

Timepoint
3 mounth

Method of measurement
Questionnaire

Intervention groups

1

Description

self care education

Category

Lifestyle

2

Description

no intervention in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Golgasht clinic

Full name of responsible person

Street address

Dr Susan Kolahi (Rheumatologist)

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

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

MSc, Nursing student

Other areas of specialty/work

Street address

3th Namazi Alley, Allameh Hashemi Blvd, Resalat Blvd, Khoy

City

Khoy

Postal code

Phone

+98 46 1235 1011

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

Ali Reza Mohajjel Aghdam

Position

MS, Nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, South Shariaty

City

Tabriz

Postal code

Phone

+98 41 1479 6770

Fax

Email

mohajjela@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zhaleh Varmaziar

Position

MSc, Nursing student

Other areas of specialty/work

Street address

3th Namazi Alley, Allameh Hashemi Blvd, Resalat Blvd, Khoy

City

Khoy

Postal code

Phone

+98 46 1235 1011

Fax

Email

zhaleh.varmaziar@yahoo.com

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