

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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)

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+98 41 1479 6770

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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

Osteoarthritise

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

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Full name of responsible person

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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