Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of self-management training versus no training on pain severity and drug usage in patients with knee osteoarthritis: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of self-management training versus no training on pain severity and drug usage in patients with knee osteoarthritis
Design
A randomized clinical trial
Settings and conduct
The eligible patients with knee osteoarthritis who will refer to Imam Hossein Hospital in Malayer City during the study period will be enrolled into the trial
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 50 to 70 years; knee osteoarthritis; literate Exclusion criteria: Using narcotic drugs; injection of analgesic in knee joint in the past 30 days; previous knee surgery; chronic diseases; a history of attending in workshop about osteoarthritis
Intervention groups
Intervention group: Routine treatment including analgesic and antiinflammatory drugs plus group training in 45-60 minutes sessions once a week for 3 weeks
Control group: Just routine treatment
Main outcome variables
(a) Assessing pain severity of knee 2 months after intervention via visual analog scale (VAS) (b) Assessing analgesic drug usage 2 months after intervention via history taking

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120215009014N200**
Registration date: **2017-12-25, 1396/10/04**
Registration timing: **retrospective**

Last update: **2017-12-25, 1396/10/04**
Update count: **0**
Registration date
2017-12-25, 1396/10/04

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-04-30, 1396/02/10
Expected recruitment end date
2017-11-01, 1396/08/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of self-management training versus no training on pain severity and drug usage in patients with knee osteoarthritis: a randomized clinical trial

Public title
Effect of self-management training versus no training on pain severity and drug usage in patients with knee

osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 50 to 70 years Knee osteoarthritis Literate

Exclusion criteria:

Using narcotic drugs Injection of analgesic in knee joint in the past 30 days Previous knee surgery Chronic diseases A history of attending in workshop about osteoarthritis

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through drawing of lots

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Province

Hamadan

Postal code

6517838695

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.UMSHA.REC.1395.581

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Assessing pain severity of knee

Timepoint

2 months after intervention

Method of measurement

Via visual analog scale (VAS)

2

Description

Assessing analgesic drug usage

Timepoint

2 months after intervention

Method of measurement

Via history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment including analgesic and antiinflammatory drugs plus group training in 45-60 minutes sessions once a week for 3 weeks

Category

Treatment - Other

2

Description

Control group: Just routine treatment including analgesic and antiinflammatory drugs

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available