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
Name
Jalal Poorolajal
Name of organization / entity
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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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Hamadan

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

Mostafa Jamshidi Zanganeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
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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

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mostafa Jamshidi Zanganeh

Position
MSc Student of Community Health

Latest degree
Master

Other areas of specialty/work
Health Promotion

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Full name of responsible person
Dr Jalal Poorolajal

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Professor of Epidemiology

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Epidemiology

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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