Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of muscle strengthening exercises on pain, physical function and morning stiffness of patients with osteoarthritis of knee : a randomized four-arm controlled trial

Protocol summary

Study aim

Determining the effectiveness of knee strengthening exercises on pain, physical function and morning stiffness of osteoarthritis of knee

Design

A clinical trial with three intervention groups and one control group, conducted on 96 patients with osteoarthritis of knee. Random sequence of 1:1:1:1 was made using Stratified, Blocked randomization (blocks of 4 and 8) by Microsoft Excel, using the RAND function.

Settings and conduct

The location of the trial was in the Rheumatology Clinic of Vali-e-Asr Hospital, Zanjan, Iran. The intervention groups performed muscle strengthening exercises around the knee joint regularly 5 days a week for 8 weeks (3 sets/day, 10-15 repetitions). Data analysts and the outcome assessor were masked.

Participants/Inclusion and exclusion criteria

Patients aged 40-70 years with osteoarthritis of knee were included in the study. simultaneous suffering from musculoskeletal diseases other than knee osteoarthritis, history of knee joint surgery, intra-articular injection of corticosteroids or hyaluronic acid in the knee joints, use of non-steroidal anti-inflammatory drugs Steroids (NSAIDs) or use of glucosamine, participating in knee joint muscle strengthening programs were considered exclusion criteria.

Intervention groups

Including three intervention groups and one control group. The first group (G1) underwent quadriceps strengthening exercises, the second group (G2) received hamstring strengthening exercises, the third group (G3) performed strength aimed at strengthening both quadriceps and hamstring muscles groups and control group (G4) received no interventions during this period.

Main outcome variables

Score of knee pain on Visual Analogue Scale (VAS) score, Score of knee physical function on the Western Ontario and McMaster (WOMAC) Index, Score of knee morning stiffness on the Western Ontario and McMaster (WOMAC) Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220206053950N2**
Registration date: **2022-09-07, 1401/06/16**
Registration timing: **retrospective**

Last update: **2022-09-07, 1401/06/16**
Update count: **0**

Registration date

2022-09-07, 1401/06/16

Registrant information

Name

Mina Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 991 207 7996

Email address

mina.rostami1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-02-25, 1394/12/06

Expected recruitment end date

2016-04-25, 1395/02/06

Actual recruitment start date

2016-03-02, 1394/12/12

Actual recruitment end date

2016-05-20, 1395/02/31

Trial completion date

2016-05-20, 1395/02/31

Scientific title

Effectiveness of muscle strengthening exercises on pain, physical function and morning stiffness of patients with osteoarthritis of knee : a randomized four-arm controlled trial

Public title

Effectiveness of muscle strengthening exercises on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with knee osteoarthritis (grades I-III in the Kellgren-Lawrence score) Patients aged 40-70 years Patients who had pain, morning stiffness of shorter than 30 minutes, or knee crepitus.

Exclusion criteria:

Concomitant involvement with musculoskeletal diseases other than knee osteoarthritis in one or both knees within the last 6 months A history of knee joint surgery Intra-articular injection of corticosteroids or hyaluronic acid in the knee joints within the past 30 days Non-steroidal anti-inflammatory drugs (NSAIDs) or glucosamine intake within the last 30 days Participation in the muscle-strengthening programs for the knee joint within the last 6 months

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence was made by Microsoft Excel using the RAND() function of this software. A 1:1:1:1 allocation was made by an independent investigator using Blocked randomization with randomly varying blocks of 4 and 8 and stratified randomization considering Kellgren-Lawrence grade 1-2 or 3. The allocation sequence was concealed from the investigator enrolling and assessing participants in sequentially numbered, opaque, sealed envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is single-blind. The principal investigator, outcome assessor, and data collector are blinded by not informing them of the group allocation. Data analyst is kept masked by providing a blinded version of data. The care provider and the participants are not blinded. Considering the nature of the intervention, which is an exercise therapy, and the fact that the control group does not receive any intervention, naturally, it is not possible to blind the participants and care providers during the trial.

Placebo

Not used

Assignment

Parallel

Other design features

The participants were asked to regularly perform exercises 5 days a week, for 8 weeks (3 sets/day, 10-15 repetitions). To ensure regular exercising according to the instructions, the participants were provided with written instructions of the exercise programs and a specific form to record their daily exercises during 8 weeks, in addition, they were telephoned once a week by the physiotherapist, encouraging patients to properly adhere to the interventions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Room No. 22, First Floor, Ethics Committee in Biomedical, Vice-Chancellor for Research and Technology, Azadi Blvd., Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2016-02-18, 1394/11/29

Ethics committee reference number

ZUMS.REC.1394.301

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
Score of knee pain on Visual Analogue Scale (VAS) score
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after the initiation of the exercise therapy
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Score of knee physical function on the Western Ontario and McMaster (WOMAC) Index
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after the initiation of the exercise therapy
Method of measurement
Western Ontario and McMaster (WOMAC) Index

3

Description
Score of knee morning stiffness on the Western Ontario and McMaster (WOMAC) Index
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after the initiation of the exercise therapy
Method of measurement
Western Ontario and McMaster (WOMAC) Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: received home-based quadriceps strengthening exercises, regularly perform 3 sets of exercises per day, 10-15 repetitions, 5 days a week for 8 weeks.
Category
Rehabilitation

2

Description
Intervention group: received home-based hamstring strengthening exercises, regularly perform 3 sets of exercises per day, 10-15 repetitions, 5 days a week for 8 weeks.
Category
Rehabilitation

3

Description
Intervention group: received home-based strengthening both quadriceps and hamstring muscles groups, regularly perform 3 sets of exercises per day, 10-15 repetitions, 5 days a week for 8 weeks.
Category
Rehabilitation

4

Description
Control group: did not receive the intervention during this period.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr Hospital, Zanjan University of Medical Sciences
Full name of responsible person
Alireza Sadeghi
Street address
Vali-e-Asr Hospital, Vali-e-Asr square, Zanjan
City
Zanjan
Province
Zanjan
Postal code
45157-77978
Phone
+98 24 3377 0801
Fax
+98 24 3377 0751
Email
valiasr@zums.ac.ir
Web page address
https://valiasr.zums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Samad Nadri
Street address
Zanjan University of Medical Sciences, Zanjan, Sobouti Blvd.
City
Zanjan
Province
Zanjan
Postal code
4513956184
Phone
+98 24 3315 6141

Email
Research@zums.ac.ir
Web page address
https://zums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Mina Rostami
Position
General physician
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
No. 4511, Helal 1Alley, Avesta Ave., Phase 3, Golshahr Town
City
Zanjan
Province
Zanjan
Postal code
4514151659
Phone
+98 991 207 7996
Email
mina.rostami1373@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mina Rostami
Position
Family Physician
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
No. 4511, Helal 1 Ave, Golshahr, Zanjan.
City
Zanjan
Province
Zanjan
Postal code
4514151659
Phone
+98 991 207 7996
Fax
Email
mina.rostami1373@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mina Rostami
Position
Family Physician
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
No. 4511, Helal 1 Ave, Golshahr, Zanjan.
City
Zanjan
Province
Zanjan
Postal code
4514151659
Phone
+98 991 207 7996
Fax
Email
mina.rostami1373@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available