Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The Effect of Neruomuscular Exercises in Combination with Cognitive-Motivational and Mindfulness Interventions on Pain, Function, Neurofeedback Factores, Kinesiophobia, and Self-Reported Knee Instability Improvement in Patients with Knee Osteoarthritis

Protocol summary

Study aim
the effect of neuromuscular Exercises with combining cognitive-motivational and mindfulness interventions on pain relief, function, Knee contracture, knee confidence, Kinesiophobia and self-report instability in patients with osteoarthritis of the knee

Design
Double-blind clinical trial (patient and researcher) with parallel groups and control group, assignment in groups based on random number (G-Power statistical software), then each number will be written in an envelope and the envelope will be placed in the bag when the patient is admitted separately Present to each patient and each patient randomly removes a number from the bag and opens it and announces it to the researcher and the number of each person is recorded in the file by the researcher) The study will be performed with a pre-test-post-test plan .

Settings and conduct
Patients were admitted to Omid Clinic under the supervision of a specialist physician in Hamadan. Study of a double-blind clinical trial (researcher and patient). The experiments were performed in the correctional movements laboratory of Bu Ali Sina University.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 40 years with a score of at least 2 in the KL criterion, chronic knee pain, failure to use any type of psychological intervention Exclusion criteria: Age under 40 years, uncontrolled diabetes (BMI> 40kg / m2), neuromuscular disorders (stroke, stiffness, tumor, MS and Parkinson's), fractures and surgery in the lower extremities

Intervention groups
Group one: Neuromuscular exercises with motivational cognitive interventions Group 2 - Neuromuscular exercises with mindfulness and neurofeedback interventions

Main outcome variables
Pain, Physical function, Quality of life, knee proprioception, Knee contracture, Balance, knee flexion ROM, Kinesiophobia, Knee instability, Foot pressure, Neurofeedback variables

General information

Reason for update
Modify the sampling date

Acronym

IRCT registration information
IRCT registration number: **IRCT20210417050997N1**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **prospective**

Last update: **2021-07-12, 1400/04/21**
Update count: **1**

Registration date
2021-07-05, 1400/04/14

Registrant information

Name
Liana Charamahali

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-01, 1400/05/10
Expected recruitment end date
2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Neruomuscular Exercises in Combination with Cognitive-Motivational and Mindfulness Interventions on Pain, Function, Neurofeedback Factores, Kinesiophobia, and Self-Reported Knee Instability Improvement in Patients with Knee Osteoarthritis

Public title
The Effect of Neruomuscular Exercises in Patients with Knee Osteoarthritis
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 40 years Having clinical criteria for osteoarthritis of the knee of the College of Rheumatology Have a score of at least 2 on the Kelgren and Lawrence criteria Chronic knee pain for at least 3 months Pain score 8-6 of the VAS scale Without use any type of psychological intervention / other counseling during periods that subjects are studying.
Exclusion criteria:
Age under 40 years Body mass index greater than or equal to (BMI> 40kg / m2), Additional orthopedic injuries in the lower extremities Neuromuscular disorders that interfere with daily functioning (such as stroke, uncontrolled muscle stiffness, MS and Parkinson's) that interfere with the exercise program Fractures and surgery in the lower extremities Taking psychiatric medication or seeing a behavioral specialist in the past six months that prevents you from exercising
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects will be randomized based on Random Number Generator software and then assigned to three groups based on SNOSE allocation concealment. Participants will be randomly assigned to one of the groups of neuromuscular exercises with motivational cognitive interventions, neuromuscular exercises with mindfulness interventions and control group. So that 15 people were identified for group one, 15 people for group two and 15 people for control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the researcher will have no information about the exercises and interventions assigned to the groups, the subjects will be unaware of the existence of parallel groups, as well as the possibility of not informing the person who is analyzing the data. There will be groups and exercises assigned to them
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commitee of Kermanshah University of Medical Sciences
Street address
Center No. 2, Shahid Beheshti Blvd, Kermanshah Town
City
Kermanshah
Province
Kermanshah
Postal code
6715663137
Approval date
2021-02-24, 1399/12/06
Ethics committee reference number
IR.RAZI.REC.1400.006

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17.2
ICD-10 code description
Bilateral post-traumatic osteoarthritis of knee

Primary outcomes

1

Description
Evaluation of pain on a visual scale of pain

Timepoint
Before the intervention, after 45, 60 days after the start of Neuromuscular Exercises
Method of measurement
visual scale of pain(VAS)

Secondary outcomes

1

Description
Function
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Western Ontario and McMasters Universities Osteoarthritis Index(WOMAC)

2

Description
Quality of Life
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
The World Health Organization Quality of Life(SF36)

3

Description
Kinesiophobia
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Tampa scale

4

Description
Knee contracture
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Universal goniometer

5

Description
Balance
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Berg balance scale-Biodex Stability System (BSS)

6

Description
Neurofeedback factors
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
With ProCamp Infini device and Infinity Biography software

7

Description
Sole pressure distribution
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
with foot pressure measurement system(FScan II)

8

Description
Knee instability
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Felson Questionnaire

9

Description
knee proprioception
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Universal goniometer

10

Description
knee flexion (ROM)
Timepoint
Before the intervention, after 45, 60 days after the start of Neruomuscular Exercises
Method of measurement
Universal goniometer

Intervention groups

1

Description
Intervention group: Neuromuscular Exercises with Motivational Cognitive Interventions
Category
Other

2

Description
Intervention group: Neuromuscular Exercises with Mindfulness and Neurofeedback Interventions
Category

Other

3

Description
Control group: Neuromuscular training group In this group, exercises will be performed three times a week for 6 weeks and 60 minutes in 2 to 3 sets with 10-15 repetitions and rest and three levels between exercises and sets. Difficulty was considered for each exercise. These exercises will be performed on both healthy and diseased feet, although the focus is on the injured foot.
Category
Other

4

Description
Intervention group 1: Neuromuscular exercises with cognitive-motivational interventions such as control group Neuromuscular exercises in addition to ten - 15 minutes of motivational interview exercises in the form of motivational speeches designed according to the table and showing motivational images and functional images to the elderly in person and online In 8 sessions along with 8 weeks of neuromuscular training
Category
Other

5

Description
Intervention group 2 :Performing neuromuscular exercises Like the control group, with mindfulness exercises based on stress reduction for ten to fifteen minutes per session along with 8 weeks of neuromuscular exercises
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid specialized and sub-specialized clinic
Full name of responsible person
Alireza Fazaeli
Street address
Omid Specialized Clinic next to Payam Hall, Sabad Bafan Street, Palestine Square, Hamedan Town
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Web page address

Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Email
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razi University
Proportion provided by this source
25
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
Razi University
Full name of responsible person
Liana Chaharmahali
Position
student
Latest degree
Master
Other areas of specialty/work
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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