

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Effect of Exercise Program on Improving Quality of Life and Sleep Quality in the Elderly with Osteoarthritis of the Knee

Protocol summary

Study aim

Determining the effect of exercise program on sleep quality and quality of life in patients with osteoarthritis of the knee

Design

In this single-blind two arms parallel-group randomized trial, 70 patients are selected by convenience sampling and then randomly assigned to the intervention and control groups.

Settings and conduct

This clinical trial is performed in the orthopedic clinic of Allameh Bohlool Gonabadi Hospital. First, the quality of sleep and quality of life are measured. The intervention group will undergo exercise in the clinic for 4 weeks. 4 weeks later, exercise is done at home with the presence of the researcher. Then the quality of life and quality of sleep will be evaluated and compared in two groups. No intervention is performed for the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Over 60 years of age, ability to answer questions Physically and mentally, and participate in sports exercises based Exclusion criteria: Having health problems affecting exercise , osteoporosis

Intervention groups

First, the Pittsburgh Sleep Quality Index (PSQI) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) are completed by the intervention group and the control group. The intervention group will undergo a training program for 4 weeks (one 30-minute session per week). 4 weeks later, exercise is done at home with the presence of the researcher. Then the mentioned questionnaires will be evaluated and compared in two groups.

Main outcome variables

sleep quality; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210129050172N1**
Registration date: **2021-02-21, 1399/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

Sara Safarnia Shahri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 6841

Email address

safarniasara@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-30, 1399/11/11

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Exercise Program on Improving Quality of Life and Sleep Quality in the Elderly with Osteoarthritis of the Knee

Public title

Investigating the effect of exercise program on improving sleep quality and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have the criteria of the American College of Rheumatology in terms of clinical and radiographic
Experiencing knee pain most days of the last month
Ability to walk independently and perform daily activities independently
Ability to answer the questionnaire's questions physically and mentally
Physical and mental ability to participate in sports exercises based on the diagnosis of the treating physician
Stability of blood pressure to participate in the study

Exclusion criteria:

Symptoms of knee lock
Knee surgery and replacement in the last 6 months
Severe knee deformity
History of knee malignancy, wound and infection around the knee, history of knee fracture, knee hypermobility and instability
Existence of metabolic and endocrine disorders such as diabetes, thyroid disease
Having health problems affecting home exercise such as uncontrolled high blood pressure, heart disorder, brain disorder, shortness of breath, arrhythmia, severe vision problems.
Chronic use of a knee brace, cane, walker or wheelchair
Corticosteroid injection during the last 30 days
Injection of hyaluronic acid into the symptomatic joint within the last six months
Osteoporosis

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are assigned to the study groups (intervention and control) by blocking randomization method with 4 blocks.
Randomization tool:
<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

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 Shahed University

Street address

Shahed university – Opposite Holy Shrine of Imam Khomeini- Khalij Fars Expressway – Tehran - Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2021-01-25, 1399/11/06

Ethics committee reference number

IR.SHAHED.REC.1399.145

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

Quality of life in KOOS and SF12 questionnaires

Timepoint

before the intervention and two months after the exercise program

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS);
12-Item Short Form Health Survey (SF-12)

2

Description

quality of sleep in Pittsburgh Sleep Quality Index (PSQI)

Timepoint

before the intervention and two months after the exercise program

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the Pittsburgh Sleep Quality Index (PSQI) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) are completed by the intervention group. The intervention group will undergo a training program for 4 weeks (one 30-minute session per week). 4 weeks later, exercise is done at home with the presence of the researcher. Then the mentioned questionnaires will be evaluated and compared in this group. Exercises will be presented in 4 sessions of 30 minutes. The first session includes 7 exercises to strengthen the quadriceps muscles (such as intermittent contraction and relaxation of this muscle, standing on one foot and bringing the heel of the other foot closer to the small serine muscle, mini-squat movement, bridge exercises, straight leg raising exercises and ...). The second session includes 3 leg muscle stretching exercises (such as gentle leg stretching, standing on the wall with one leg in the back and the other leg in the front stretching, etc.) and 2 hamstring muscle stretching exercises (hamstring muscle stretching and Improve the range of motion of the knee by lying down and bringing one foot closer to the chest with the hands or a strap). The third session includes 2 exercises to strengthen the large serine muscle to control the torso, leg stability and balance while standing and walking (including strengthening these muscles while lying on the abdomen and contracting the buttocks and then raising one leg, sitting on a chair and while The knee is bent, lifting it off the floor) and 3 exercises to strengthen the legs (such as strengthening the legs by

Category

Rehabilitation

2

Description

Control group: No intervention is performed for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlool Gonabadi Hospital

Full name of responsible person

Sara Safarnia Shabri

Street address

No. 8 , Naser Khosrow 17 Alley. Naser Khosrow Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Persian Gulf Highway (Tehran - Qom), facing the shrine Motahar Imam Khomeini, Shahed University

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Web page address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

sara safarnia shabri

Position

M.Sc Student In Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahed University

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Position

Assistant Professor

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Ph.D.

Other areas of specialty/work

Nursery

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Position

Master of Science

Latest degree

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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