Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Shahri

Street address

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

City

Gonabad

Province

Razavi Khorasan

Postal code

9691845435

Phone

+98 51 5722 6841

Email

safarniasara@gmail.com

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

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 3565

Fax

+98 21 5121 3564

Email

info@shahed.ac.ir

Web page address

https://www.shahed.ac.ir/

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 shahri

Position

M.Sc Student In Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Tehran province in front of Imam Khomeini shrine, Persian Gulf freeway

City
Tehran

Province
Tehran

Postal code
3319118651

Phone
098 21 51213565

Fax
+98 21 5121 3564

Email
publicrelation@shahed.ac.ir

Web page address
https://www.shahed.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Mohammad Reza Heidari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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

City
Tehran

Province
Tehran

Postal code
3319118651

Phone
+98 21 5121 3565

Fax
+98 21 5121 3564

Email
mheidari@shahed.ac.ir

Web page address
https://www.shahed.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Sara Safarnia Shahri

Position
Master of Science

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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

City
Gonabad

Province
Razavi Khorasan

Postal code
3319118651

Phone
+98 51 5722 6841

Fax

Email
safarniasara@gmail.com

Web page address
https://www.shahed.ac.ir/

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