Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Benson relaxation technique on sleep quality, anxiety, stress and depression in the elderly with knee osteoarthritis

Protocol summary

Study aim
Determining the effect of Benson's relaxation method on the quality of sleep, anxiety, depression and stress of the elderly with knee osteoarthritis

Design
A clinical trial has a control group. 86 patients with conditions to enter the study were selected and assigned to the groups under study by block randomization method and block size of four.

Settings and conduct
The statistical population is all elderly people over 60 years old with knee osteoarthritis who refer to the orthopedic clinic of Shahid Mostafa Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Entry conditions include 1- age over 60 years old; 2- ability to complete the questionnaire; 3- not having dementia (dementia) by obtaining a score of more than 7 from the Abbreviated Mental Test Score (AMTS); 4- obtaining a higher overall score of 5 (meaning poor sleep quality) by the PSQI scale. The conditions of non-entry include 1- stopping relaxation exercises by the elderly; 2- Suffering from any kind of disease that prevents relaxation exercises; 3- death or travel.

Intervention groups
Intervention: The patient is asked to do Benson's relaxation exercises for 20 minutes twice a day for one month. Control: In the control group, no intervention is done and the patient receives routine treatment and care.

Main outcome variables
Sleep quality; stress; anxiety; depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230304057605N1**
Registration date: **2023-04-11, 1402/01/22**
Registration timing: **prospective**

Last update: **2023-04-11, 1402/01/22**
Update count: **0**

Registration date
2023-04-11, 1402/01/22

Registrant information

Name
Mohammad Reza Keyhani Dehnavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3309 1461

Email address
mohammadrezakeyhani76@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-19, 1402/01/30

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Benson relaxation technique on sleep quality, anxiety, stress and depression in the elderly with knee osteoarthritis

Public title
The effect of Benson relaxation technique on sleep

quality, anxiety, stress and depression in the elderly with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years old Ability to complete the questionnaire Obtaining a total score of more than 5 (meaning low sleep quality) by PSQI

Exclusion criteria:

Dementia

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are included in the study by block randomization and parallel allocation. First, by assigning the letter A to the test group and the letter B to the control group, the six states ABBA, BABA, ABAB, BBAA, AABB, BAAB are written on separate sheets and thrown into a container. By chance, one of these sheets is taken out of the container and the combination written on it is remembered, and that sheet is thrown into the container again. Because the sample size in this study is 86 patients, this procedure is repeated 22 times and each time the composition written on each sheet is noted in the sequence of the composition written on the previous sheet. Then, a number from 1 to 86 is assigned to each of the letters in the order of the letters noted in a row. Each letter is placed in an envelope and the number of that letter is written on the envelope. Every time a disease is selected, one of these envelopes is opened according to the number written on the envelope and the patient is placed in the test or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants

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, At the beginning of Tehran- Qhom Road

City

Tehran

Province

Tehran

Postal code

991767994955

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

IR.SHAHED.REC.1401.164

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M19.90

ICD-10 code description

Unspecified osteoarthritis, unspecified site

Primary outcomes

1

Description

Sleep quality score in Pittsburgh Sleep Quality Index

Timepoint

Before and after the intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

2

Description

Depression score in Depression, Anxiety and Stress Scale

Timepoint

Before and after the intervention

Method of measurement

Depression, Anxiety and Stress Scale

3

Description

Anxiety score in Depression, Anxiety and Stress Scale

Timepoint

Before and after the intervention

Method of measurement

Depression, Anxiety and Stress Scale

4

Description

Stress score in Depression, Anxiety and Stress Scale

Timepoint
Before and after the intervention
Method of measurement
Depression, Anxiety and Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patient is asked to sit, close his eyes, gradually relax his body muscles from the tip of the toes to the face, inhale through the nose and slowly exhale through the mouth. Be aware of your breathing and repeat in your mind the word that always reminds you of peace in every exhalation. The patient continues these exercises for 20 minutes. After this period, they keep their eyes closed for a few minutes and then open their eyes. This exercise is done twice a day for 1 month.
Category
Treatment - Other

2

Description
Control group: No intervention is performed in the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mustafa Khomeini Hospital
Full name of responsible person
Mohammad Reza Keyhani Dehnavi
Street address
No. 9, Italy St., Palestine St., Keshavarz Blvd., Valiasr Square
City
Tehran
Province
Tehran
Postal code
1416643491
Phone
+98 21 8896 6130
Email
mohammadrezakeyhani76@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr. Shahriar Bijani
Street address
Shahed University, facing the Holy Shrine Imam Khomeini, Persian Gulf highway (Tehran-Qom),
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 5105
Email
info@shahed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
Mohammad Reza Keyhani Dehnavi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahed University, in front of the holy shrine of Imam Khomeini (RA), at the beginning of Tehran-Qom highway
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 3560
Fax

+98 21 5121 3564

Email

info@shahed.ac.ir

Web page address

http://site.shahed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohammad Reza Heidari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahed University, facing the Holy Shrine Imam Khomeini, Persian Gulf highway (Tehran-Qom),

City

Tehran

Province

Tehran

Postal code

18735/136

Phone

+98 21 5121 2146

Email

mheidari@shahed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohammad Reza Heidari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahed University, facing the Holy Shrine Imam Khomeini, Persian Gulf highway (Tehran-Qom)

City

Tehran

Province

Tehran

Postal code

18735/136

Phone

+98 21 5121 2146

Email

mheidari@shahed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Documents published in articles

From where data/document is obtainable

mheidari@shahed.ac.ir

What processes are involved for a request to access data/document

Apply via academic email

Comments