

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

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No. 9, Italy St., Palestine St., Keshavarz Blvd., Valiasr Square

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**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),

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**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

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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## 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**