

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### **A comparative study of the effect of sleep hygiene program training and foot reflexology massage on the quality of sleep and quality of life of the elderly: a randomized controlled clinical trial study**

#### **Protocol summary**

##### **Study aim**

Comparison of the effect of sleep hygiene training and foot reflexology massage on the quality of sleep and quality of life of the elderly referring to day care centers in Sari city in 2014

##### **Design**

Clinical trial with control group, with intervention groups 1 and 2, randomized, on 120 patients. Envelopes will be used for randomization.

##### **Settings and conduct**

The intervention will be carried out in daily care centers for the elderly in Sari city, and a group of 40 people will receive sleep hygiene training, and a group of 40 people will also receive foot massage, and a group of 40 people will be the control group.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria Having a calendar age of 60 years and older and living in Sari city, having sleep problems (sleep quality score more than 5), being able to communicate, getting a score of 7 (seven) or more in the AMT cognitive test, not having a history of psychosis according to the diagnosis of a specialist doctor. No complications in the legs such as fractures, wounds and skin, sensory and movement disorders and written informed consent to participate in the desired courses and visit the center daily for at least the last three months and the procedure is not harmful for the elderly according to the diagnosis of the center doctor. Exclusion criteria Intolerance and restlessness and anxiety of the elderly, hospitalization, absence of more than two sessions, occurrence of complications or disorder or special disease during the last month during the study process.

##### **Intervention groups**

Sleep health education intervention group  
Foot reflex massage intervention group  
control group

##### **Main outcome variables**

Quality of life: Quality of sleep

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20221106056420N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

##### **Registration date**

2023-09-02, 1402/06/11

##### **Registrant information**

##### **Name**

Mohammad Taha Saadati Rad

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 11 3311 9074

##### **Email address**

m.saadatirad@mazums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2023-09-07, 1402/06/16

##### **Expected recruitment end date**

2023-10-30, 1402/08/08

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

## Scientific title

A comparative study of the effect of sleep hygiene program training and foot reflexology massage on the quality of sleep and quality of life of the elderly: a randomized controlled clinical trial study

## Public title

A comparative study of the effect of sleep hygiene program training and foot reflexology massage on the quality of sleep and quality of life of the elderly

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having a calendar age of 60 years and older living in Sari city, having sleep problems (sleep quality score more than 5 being able to communicate getting a score of 7 (seven) or more in the AMT cognitive test not having a history of psychosis according to the diagnosis of a specialist doctor No complications in the legs such as fractures, wounds and skin, sensory and movement disorders written informed consent to participate in the desired courses visit the center daily for at least the last three months the procedure is not harmful for the elderly according to the diagnosis of the center doctor

### Exclusion criteria:

The presence of skin problems and wounds in the legs Inability to communicate Having a cognitive problem

## Age

From **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be randomly assigned to three control and intervention groups using a 3-way block method (using sealed opaque envelopes). In this way, 120 envelopes contain 3 ABC codes (code A for massage intervention, code B for training intervention and code C for the control group) will be prepared. 40 envelopes will be prepared from each of the 6 cases of random placement of these letters together, and they will be randomly selected by lottery. Intervention and control groups will be allocated.

## 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

Research Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Research Assistant, Moalem Square, Mazandaran University of Medical Sciences, Mazandaran, Sari, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

0000000000

#### Approval date

2023-08-14, 1402/05/23

#### Ethics committee reference number

IR.MAZUMS.REC.1402.317

## Health conditions studied

### 1

#### Description of health condition studied

sleep disorder

#### ICD-10 code

G47.9

#### ICD-10 code description

Sleep disorder, unspecified

## Primary outcomes

### 1

#### Description

Quality of Sleep

#### Timepoint

Before the intervention, after the end of the intervention, one month after the end of the intervention

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire

### 2

#### Description

Quality of life

#### Timepoint

Before the intervention, after the end of the intervention, one month after the end of the intervention

#### Method of measurement

Lipad Quality of Life Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1 : Sleep hygiene education: The education will be held in groups of two to five people at the daily care centers in Sari. The duration of the training session is an average of one hour, which will be provided by the researcher. The teaching method will be lecture, group discussion and question and answer. Educational aids such as video projectors, slides, and pamphlets will contain pictures of the principles of sleep hygiene. In this session, the educational content includes the importance of sleep in the life of the elderly, changes in sleep during old age, and the sleep hygiene program (including nutrition, activity, sleep environment, setting the schedule). Sleep will be provided for the elderly. At this stage, the educational pamphlet, which will contain the above issues and will be prepared using authentic books and articles, will be provided to the elderly. If the elderly are illiterate, the experts will prepare the educational pamphlet for the elderly. The elderly read

#### Category

Rehabilitation

### 2

#### Description

Intervention group2: Foot reflex massage: To implement reflex foot massage intervention, the researcher after fully explaining the procedure and obtaining informed consent, it is performed for 30 minutes on both feet (15 minutes for each foot) and during 3 sessions. All interventions are performed by the researcher.

#### Category

Treatment - Other

### 3

#### Description

Control group: does not receive any intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sarai Mehr Day Care Center for the Elderly

##### Full name of responsible person

Asghar Nourozi

##### Street address

6 Imam Reza Street, Imam Reza Street, Serai Mehr Center

##### City

Sari

##### Province

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##### Postal code

1234567890

##### Phone

+98 911 353 9077

##### Email

Asg.noruzi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Pedram Ebrahim Nezahad

##### Street address

Sari, Moalem Square

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##### Province

Mazandaran

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1234567890

##### Phone

+98 11 3448 4854

##### Email

Research@mazums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mazandaran University of Medical Sciences

#### 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ehteram Sadat Ilali

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Geriatrics

##### Street address

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Mohammad Taha Saadati Rad  
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Msc Student

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4817875931  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

-

### When the data will become available and for how long

-

### To whom data/document is available

-

### Under which criteria data/document could be used

-

### From where data/document is obtainable

-

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

-

### Comments