

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Foot Reflexology on Severity of Frailty and Quality of Sleep in Frail Older Adults

#### Protocol summary

##### Study aim

Determining The Effect of Foot Reflexology on Severity of Frailty and Quality of Sleep in Frail Older Adults

##### Design

The current study is a randomized clinical trial that will be conducted in two control and intervention groups in parallel. The sample size of 30 people in each group was calculated. The participants will be randomly selected among the elderly who meet the entry criteria and refer to the health centers affiliated to Kashan University of Medical Sciences. Related health centers are also selected randomly from each region of Kashan. Randomization will be done in a simple way. Random Number Generator software version 1.4 will be used to randomize and divide groups.

##### Settings and conduct

In this study, Frailty and sleep quality of Frailty Older Adults in Kashan city will be investigated. The questionnaires will be completed in the first week and one week after the end of the intervention. Finally, the data will be analyzed by the analyzer. Blinding will be done for the statistical researcher of the study to analyze the study data.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Older Adults over 60 years old with frailty criteria Failure to enter: Frail Older Adults with dementia or leg ulcers

##### Intervention groups

The intervention group will receive foot reflexology massage for 8 weeks. In the control group, the common programs and programs of comprehensive health service centers for the elderly; Done.

##### Main outcome variables

Frailty, sleep quality

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230225057526N1**

Registration date: **2023-02-28, 1401/12/09**

Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**

Update count: **0**

#### Registration date

2023-02-28, 1401/12/09

#### Registrant information

##### Name

salman rahnama

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3339 3844

##### Email address

slmanrhnma@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-03-01, 1401/12/10

#### Expected recruitment end date

2023-03-11, 1401/12/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of Foot Reflexology on Severity of Frailty and Quality of Sleep in Frail Older Adults

#### Public title

The Effect of Foot Reflexology on Severity of Frailty and Quality of Sleep in Frail Older Adults

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

1. Patients must be at least 60 years old. 2. Patients with Frailty conditions who score at least 3 from Farid's questionnaire 3. Patients who do not have a history of foot reflexology or foot massage. 4. Be free of any wounds on the legs (no deformity, calluses or corns, fissures, active thrombosis or phlebitis, varicose veins, recent ankle trauma, sprains, fractures, inflammation or infection). 5.No abnormal symptoms such as sensitivity to pain under the pressure of the intervening finger, a clear change in skin color (for example, reddish brown/brown/dark brown/black), swelling (meaning creating a convex shape), hollowing ( creating a concave shape), hollows using specific finger pressure should be seen in the legs. 6.Be able to communicate vigilantly and verbally in Persian. 7. Tend to participate in the study Willingly. 8. Not suffering from dementia or getting a score higher than 22 from the M.M.S.E questionnaire. 9. Not having diabetes. 10. Not using Opiates.

#### **Exclusion criteria:**

Hospitalization of the Older Adult Use other complementary treatments.

### **Age**

From **60 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Randomization will be done in a simple way. Random Number Generator software version 1.4 will be used to randomize and divide groups. In this software, the smallest and largest number and the required number of random numbers are determined. The numbers obtained in the first group will be assigned for the control group and the same numbers group will be assigned for the intervention group.

### **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 in Research Faculty of Nursing and Midwifery, Health and Paramedicine- Kashan Unive

##### **Street address**

Doctor's Boulevard- Qutb Ravandi Boulevard -Kashan

##### **City**

kashan

##### **Province**

Isfahan

##### **Postal code**

8715973474

#### **Approval date**

2023-02-13, 1401/11/24

#### **Ethics committee reference number**

IR.KAUMS.NUHEPM.REC.1401.087

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Frail Older Adults

#### **ICD-10 code**

Z00.0

#### **ICD-10 code description**

Encounter for general adult medical examination

## **Primary outcomes**

### 1

#### **Description**

Frailty score from Farid questionnaire

#### **Timepoint**

Measuring of frailty at the beginning of the study and re-measuring of frailty one week after the intervention. The intervention will be carried out for eight weeks. The questionnaire will be completed in the first week and the 9th week

#### **Method of measurement**

Frailty will be measured by a 5-item Farid questionnaire(FSC=Frailty Syndrome Checklist 5-Items). No Frailty (score 0), pre-Frailty (score 1-2) and Frailty (score 3-5)

### 2

#### **Description**

Sleep quality score from Pittsburgh questionnaire

#### **Timepoint**

Measurement of sleep quality at the beginning of the study and re-measurement one week after the intervention. The intervention will be carried out for eight weeks. The questionnaire will be completed in the first week and the 9th week

#### **Method of measurement**

The measurement of sleep quality will be done by the

Pittsburgh questionnaire. The score obtained from the Pittsburgh questionnaire (score between 0 and 21), a score higher than 5 indicates unfavorable sleep quality, the higher the score of a person indicates unfavorable sleep quality.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The participants of the Intervention group in the first session receive general information about foot reflexology, the history of this method and its benefits, and their possible questions are answered. Then, the initial questionnaires will be completed for them, and the technique implementation guide, intervention meeting schedule sheet, and communication methods will be provided to the participants. The test group receives foot reflexology massage by the researcher once a week for two months. The time of each session will be 30 minutes. The intervention will be done for each person on a certain day of the week done in a bright and quiet room at the health center. If the person is not able to go to the health center, the researcher goes to their house and tries to do the intervention in a quiet and comfortable room. To implement the intervention, the participant is placed on the bed in a relaxed position, then the researcher sits at the bottom of the bed and rubs the surfaces of his palms together to become warm. Then the back and soles of the feet will be massaged. In order to carry out the intervention, the researcher hold the heel with his left hand and pointed with the thumb and forefinger of his right hand on the corresponding reflex points (solar plexus, pituitary gland, eye, ear, brain, spine, sciatic nerve, heart, thyroid, hip joint). (although there is no clear information about the reflex points, these points were chosen based on past studies and their effectiveness) this work for 30 minutes on both legs (15 minutes for each leg) ) is done. The researcher, at the first 5 minutes, will perform a gentle massage of the soles of the feet and each reflex point will receive a minute of proper pressure. If the elderly person does not participate for the massage at the appointed time, the compensatory session will be held at the earliest possible time, and the rest of the sessions will be carried out according to the previous schedule, and all the elderly must receive 8 intervention sessions.

#### Category

Rehabilitation

### 2

#### Description

Control group: for the control group, common programs of comprehensive health service centers done for the older adults. The common programs of these centers include screening in the electronic health system (SEB).

In this system, the older adults are routinely screened for high blood pressure, nutrition, depression, falls and imbalance, heart and brain strokes, colon cancer and vaccination. In the screenings, the needs of the elderly are determined and based on that, they are trained and referred to the doctor. One week after the last intervention session (because no intervention is done in the control group, eight weeks after filling out the initial questionnaire), questionnaires will be completed for them again.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashan University of Medical Sciences

##### Full name of responsible person

Cyrus Saki

##### Street address

Doctor's Boulevard- Qutb Ravandi Boulevard -Kashan

##### City

kashan

##### Province

Isfahan

##### Postal code

8715973474

##### Phone

+98 31 5558 9444

##### Email

info@kaums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Cyrus Saki

##### Street address

Doctor's Boulevard- Qutb Ravandi Boulevard -Kashan

##### City

kashan

##### Province

Isfahan

##### Postal code

8715973474

##### Phone

+98 31 5558 9444

##### Email

info@kaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

**Title of funding source**

Faculty of Nursing and Midwifery, Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Salman Rahnama

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Plate 131. In front of 12th Imami School.Martyrs' field  
Jami St

**City**

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**Province**

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**Postal code**

8137777591

**Phone**

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**Email**

slmanrhnma@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Salman Rahnama

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Salman Rahnama

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Province**

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**Phone**

+98 31 3339 3844

**Fax****Email**

slmanrhnma@gmail.com

**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**

All data is potentially shareable after de-identifying individuals

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

The access period starts from 1402 and the access period starts 2 months after the results are printed

**To whom data/document is available**

All people are allowed to send requests to receive data or other study documents.

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

There are no properties available.

**From where data/document is obtainable**

Salman Rahma's email address is  
slmanrhnma@gmail.com

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

A week

**Comments**