Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Isfehan

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-msuring 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
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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
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Salman Rahnama
Position
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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
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 Rahnma's email address is slmanrhnma@gmail.com

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

A week

Comments