Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of reflexology and foot bath to improve sleep quality in elderly

Protocol summary

Summary

The aim of this study is to determine the effect of reflexology and foot bath to improve sleep quality in elderly. Aged 60 years and older referred to Tabriz health centers and older people that are healthy in all aspects of touch; hearing; sight and mental were include in study and seniors who were taking sleep medications or herbal medicine for sleep disorders or other alternative and complementary therapies used for sleep disorders were excluded. This study is a single-blind clinical randomized controlled trial that using of the Pittsburgh sleep qualit questionnaire whit two groups (reflexology and foot bath) and a control group will be performed on 96 elderly. Intervention sessions of reflexology as 6 weeks, once a week for 20 minutes with olive oil for each leg will be done. In foot bath group after training; participants will be asked 6 weeks every night one hour before the usual time sleeping soaking your feet 10 centimeters above the ankle for 20 minutes in warm water with a temperature of 41 to 42 degrees celsius with the temperature on the thermometer that has been flagged by the researcher. participants will follow up by phone. Questionnaire for all three groups after 6 weeks to be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210046918N13**
Registration date: **2013-01-03, 1391/10/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-03, 1391/10/14

Registrant information

Name
Alehe Seyedrasooli
Name of organization / entity
Faculty of Nursing & Midwifery
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Deputy for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-20, 1392/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of reflexology and foot bath to improve sleep quality in elderly

Public title

Quality of Sleep in Elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Aged 60 years and older; Elderly resident referring to Tabriz health centers and suburbs;Relative independence in activities of daily living; Having the desire and interest to participate in the

study; Not working at night Exclusion criteria:Taking sleeping medications or herbal remedies for sleep disorders; Having a mental illness and Severe nacturia and Asthma; Having trouble hearing and vision; The use of other complementary therapies such as relaxation effects and hot showers and massage other body parts and music and sports and walk before bedtime to improve sleep quality;Having diabetes; having a sensory impairment

Age
From **60 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Deputy for Research, Tabriz University of Medical Sciences

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Deputy of Medical Sciences University of Tabriz

City
Tabriz

Postal code

Approval date
2012-11-30, 1391/09/10

Ethics committee reference number
45/7/1047

Health conditions studied

1

Description of health condition studied
Quality of Sleep

ICD-10 code
G47.9

ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
Quality of Sleep

Timepoint
Before intervention and 6 week after intervention

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
Reflexology intervention will be by the researcher for 6 weeks; once a week for 20 minutes with olive oil for each foot.

Category
Other

2

Description
In foot bath group after training; participants will be asked 6 weeks every night one hour before the usual time sleeping soaking your feet 10 centimeters above the ankle for 20 minutes in warm water with a temperature of 41 to 42 degrees celsius with the temperature on the thermometer that has been flagged by the researcher.

Category
Other

3

Description
In control group was not intervention performed.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person
Khadijeh Nasiri

Street address
Shariety South St ; Faculty of Nursing & Midwifery

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Kazem Shakori

Street address

Deputy of Medical Sciences University of Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariety Faculty of Nursing & Midwifery

Full name of responsible person

Alehe Seyyedrasooli

Position

Ms

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty