

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Effect of Foot bath on Sleep Quality in Elderly

Protocol summary

Study aim

To determine the effect of foot bath on elderly sleep quality

Design

Single-blinded Randomized Controlled Clinical trial on 45 elderly urban home residents, aged 60 or above, allocated in three groups (two intervention and one control group) will be recruited. Allocation will be done using permutation blocks randomization method.

Settings and conduct

The trial will be done in elders' house to assess the effect of foot bath on their sleep quality among three groups (two intervention and one control groups). Sleep quality will be evaluated using Pittsburgh Sleep Quality Index (questionnaire). Blinding will be achieved by using research assistant who is not informed of grouping and sleep quality scores, and assess the elders' sleep quality on 2nd and 4th week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60 or above, being relatively independent in activities of daily living, Ability to communicate, Lacking acute illness Exclusion criteria: Having night shift, Use of other supportive and complementary therapies, Diabetic over 10 years

Intervention groups

After training the elders in foot bath groups, they will be asked to immerse their feet 10 centimeters above the ankle, for 10 minutes in the 40°C water (group 1), and 37°C (group 2) for 2 weeks, every night, an hour before their usual sleeping time. To help subjects control water temperature, they will be given ink-marked thermometers. Control group will receive no intervention.

Main outcome variables

Subjects' sleep quality scores achieved by administering Pittsburgh Sleep Quality Index (questionnaire) at the beginning of the study; and on the 2nd and 4th week.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180405039197N1**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Zohreh Ebrahimzadeh moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7095

Email address

z.ebrahimzadeh@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-23, 1397/02/03

Expected recruitment end date

2018-08-25, 1397/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot bath on Sleep Quality in Elderly

Public title

Elderly Sleep Quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 or over Being independent in activities of daily living Having a companion to help the elderly during intervention Ability to communicate (awareness of time, place, and people) Lacking acute illness

Exclusion criteria:

Having night shifts Use of other supportive and complementary therapies Diabetic more than 10 years Having peripheral vascular problems and neuropathies

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation will be done using permutation blocks randomization method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Subjects' sleep quality in all groups will be evaluated using Pittsburgh Sleep Quality Index (questionnaire) at the beginning of the study by the researcher; and at the 2nd and 4th week, by researcher's assistant who is blind to the grouping and sleep quality scores.

Placebo

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

Street address

Central Building of North Khorasan University of Medical Sciences, Dolat Blvd., Bojnurd

City

Bojnurd

Province

North Khorasan

Postal code

74877-94149

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

IR.nkums.REC.1396.71

Health conditions studied

1

Description of health condition studied

Elders' Sleep Quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Elders' Sleep Quality Index Score

Timepoint

At the start, 14, and 28 days after intervention

Method of measurement

Pittsburgh Sleep Quality Index (Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Foot bath (immersing the feet 10 cm above ankle) using 40°C water, for 10 minutes, every night one hour before usual sleep time for 2 weeks.

Category

Other

2

Description

Intervention group 2: Foot bath (immersing the feet 10 cm above ankle) using 37°C water, for 10 minutes, every night one hour before usual sleep time for 2 weeks.

Category

Other

3

Description

Control group: Receives no intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

دانشگاه علوم پزشکی خراسان شمالی

Full name of responsible person

Mohammad Reza Armat

Street address

Bojnurd School of Nursing and Midwifery, Shahriar St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Kaveh Hojjat

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Grant name

1111

Grant code / Reference number

1111

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Zohreh Ebrahimzadeh Moghaddam

Position

Graduate 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

Mohammad Reza Armat

Position

Instructor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available