

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Footbath on Sleep Quality of the menopausal women: A Blinded Randomized Clinical Trial

Protocol summary

Study aim

The effect of foot bath on sleep disorder in menopausal women

Design

Blinded Randomized Clinical Trial

Settings and conduct

One-blind clinical trial will be performed on postmenopausal women referring to urban health centers in two groups of foot and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Women who have been 1-4 years old since their menopause. 2. Reading and writing literacy 3. Non-use of psychiatric medications based on patient's statements 4. Lack of chronic diseases such as diabetes, hypertension, and medical illnesses. 5. Not having mental illness
Exclusion criteria: 1- Unwilling to participate in the study 2. Hormone therapy 3. Use of other complementary methods such as herbal medicine

Intervention groups

Footbath

Main outcome variables

Score of Sleep Quality

General information

Reason for update

Acronym

FBSQ

IRCT registration information

IRCT registration number: **IRCT20190531043778N1**

Registration date: **2019-06-12, 1398/03/22**

Registration timing: **prospective**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name

Khadijeh Nasiri

Name of organization / entity

Khalkhal University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3243 2003

Email address

kh.nasiri@khalums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2019-09-05, 1398/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Footbath on Sleep Quality of the menopausal women: A Blinded Randomized Clinical Trial

Public title

Survey Footbath on Sleep Quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 1-4 years after menopause
Reading and writing skills
No psychiatric use based on the patient's own words
Lack of chronic diseases such as diabetes, hypertension and medical illnesses, etc.
Lack of mental illness

Exclusion criteria:
Unwillingness to participate in the study
Hormone Therapy
Use of other complementary therapies such as herbal remedies

Age

From **52 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment in intervention and control groups will be randomized with a 1: 1 assignment ratio in blocks 4 and 6.

Blinding (investigator's opinion)

Single blinded

Blinding description

Sampling will be done by a colleague without the knowledge of the researcher

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Khalkhal ,Universitu of Medical science

Street address

Mozafar St

City

Khalkhal

Province

Ardabil

Postal code

1761351

Approval date

2019-02-22, 1397/12/03

Ethics committee reference number

IR.khalums.rec.1397.011

Health conditions studied

1

Description of health condition studied

Sleep Disorder

ICD-10 code

F51.8

ICD-10 code description

Other sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description

Score of Sleep Quality

Timepoint

Before and After intervention

Method of measurement

PSQI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Foot bath

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of Health

Full name of responsible person

خدیجه نصیری

Street address

Mozafar St

City

Khalkhal

Province

Ardabil

Postal code

1761351

Phone

+98 45 3243 2002

Fax

+98 45 3242 1979

Email

Khadije.nasiri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

دانشکده علوم پزشکی خلخال

Full name of responsible person

Khadijeh Nasiri

Street address

Mozafar St

City

Khalkhal

Province

Ardabil

Postal code

1761351

Phone

+98 45 3243 2002

Email

khadije.Nasiri@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

دانشکده علوم پزشکی خلخال

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**

دانشکده علوم پزشکی خلخال

Full name of responsible person

khadijeh Nasiri

Position

faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Mozafar St

City

Khalkhal

Province

Ardabil

Postal code

1761351

Phone

+98 45 3243 2002

Email

khadije.Nasiri@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Khalkhal University of Medical Science

Full name of responsible person

Khadijeh Nasiri

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Mozafar St

City

Khalkhal

Province

Ardabil

Postal code

1761351

Phone

+98 45 3243 2002

Email

khadije.Nasiri@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Khalkhal University of Medical Science

Full name of responsible person

khadijeh Nasiri

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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

Undecided - It is not yet known if there will be a plan to make this available	long
Clinical Study Report	2020
Undecided - It is not yet known if there will be a plan to make this available	To whom data/document is available
Analytic Code	free access
Undecided - It is not yet known if there will be a plan to make this available	Under which criteria data/document could be used
Data Dictionary	All the conditions
Yes - There is a plan to make this available	From where data/document is obtainable
Title and more details about the data/document	Khalkhal University of Medical Sciences
It will be published in the form of the article	What processes are involved for a request to access data/document
When the data will become available and for how	Send a letter to Khalkhal Medical Sciences Research Vice-Chancellor
	Comments