Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Footbath on Sleep Quality of the menopausal women: A BlindedRandomized 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
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Iran (Islamic Republic of)
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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 BlindedRandomized Clinical Trial

Public title
Survay 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
دانشکده علوم پزشکی خلخال

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?
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

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

It will be published in the form of the article

When the data will become available and for how long

2020

To whom data/document is available

free access

Under which criteria data/document could be used

All the conditions

From where data/document is obtainable

Khalkhal University of Medical Sciences

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

Send a letter to Khalkhal Medical Sciences Research Vice-Chancellor

Comments