Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of foot reflexology massage on sleep and stress and Anxiety of nurses

Protocol summary

Study aim
Determining the effect of foot reflexology massage with sweet almond oil on nurses' sleep, stress, and anxiety.

Design
This study is a single-blind factorial clinical trial with a control group conducted on 106 nurses working in the hospital. Participants are assigned numbers randomly. odd numbers are allocated to the intervention group, and even numbersto the control group.

Settings and conduct
First, the Pittsburgh Sleep Quality Index (PSQI) and the DASS questionnaire are completed. Based on their scores, nurses who have sleep problems and experience stress and anxiety are randomly assigned to two groups. The intervention group receives training in foot reflexology massage. the statistical data analyst is blinded to the group assignments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study No allergy to sweet almond oil No use of anti-anxiety medications Exclusion criteria: Use of anti-anxiety medications and presence of edema in the leg

Intervention groups
For the foot reflex zone therapy intervention, an instructional video demonstrating the massage technique will be prepared by a specialist in traditional medicine. The researcher will provide in-person training on the specific areas of the sole to be massaged, and socks with the massage points marked on them will be given to the participants. The intervention will be carried out over three weeks in a total of nine sessions. T No intervention will be performed in the control group.

Main outcome variables
Sleep; Stress; Anxiety؛ foot reflexology massage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260601069604N1**
Registration date: **2026-07-18, 1405/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-18, 1405/04/27**
Update count: **0**

Registration date
2026-07-18, 1405/04/27

Registrant information

Name
zahra sarlak

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6550 3326

Email address
sarlak.zahra32@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-21, 1405/03/31

Expected recruitment end date
2026-08-22, 1405/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology massage on sleep and stress and Anxiety of nurses

Public title

The effect of foot reflexology massage on sleep and stress and Anxiety of nurses

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1-Willingness to participate in the study. 2-Have sleep disorders. 3-Suffer from anxiety states. 4-Minimum age for participants 22 and Maximum age 55 years old. 5-Have at least one year of clinical work experience. 6-Have no foot ulcers.

Exclusion criteria:

Taking medication to control sleep problems or anxiety edema in the foot, pregnant women

Age

From **22 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

"Participants will be randomly assigned to either the intervention group or the control group using a permuted block randomization method. To ensure an equal allocation ratio throughout the study and to prevent predictable patterns, variable block sizes (4 will be employed. The randomization sequence will be generated by an independent investigator, who is not involved in the recruitment or treatment process, using [Random Allocation Software]. To maintain strict allocation concealment, the sequence will be implemented using sequentially numbered, opaque, sealed envelopes. These envelopes will only be opened by the investigator at the time of enrollment and after obtaining informed consent, ensuring that the investigators and participants remain blinded to the allocation until the moment of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

To ensure a balanced sample size in the intervention and control groups and to prevent time-related bias, a block randomization method was used with Stata software. In this method, participants were divided into blocks of 4 such that in each block the number of individuals assigned to both groups was equal.

Placebo

Not used

Assignment

Parallel

Other design features

After preparing the list of participants and randomly selecting two intervention and control groups, the participants in the intervention group were given practical training and educational aids were provided to them. Only the intervention group was given private training on the method of performing the work. The outcome of the intervention was examined by the evaluator through the completion of questionnaires. The data analyst was blinded and did not know which sample belonged to which group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences

Street address

Farabi Hospital,Qazvin Square,Kargar St

City

Tehran

Province

Tehran

Postal code

1336616351

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.697

Health conditions studied

1

Description of health condition studied

Occupational stress and sleep quality in nursing professionals

ICD-10 code

Z56.3

ICD-10 code description

Stressful work schedule

Primary outcomes

1

Description

Nurses' sleep quality is measured using the standard Petersburg Sleep Quality Questionnaire. This questionnaire has 7 domains and its final score ranges from 0 to 21, with higher scores indicating worse sleep quality.

Timepoint

Questionnaires are completed before the start of the intervention and at the end of every 3 sessions per week (end of each week).

Method of measurement

The intervention will consist of 9 reflexology sessions,

which will be performed for 3 weeks, 3 sessions per week for each participant. The sessions will be held at home or in a hospital room (as designated) by a previously trained person under the supervision of a relevant expert. Each session will last approximately 15-20 minutes. Data will be collected via an electronic questionnaire at the end of each week after 3 sessions.

Secondary outcomes

1

Description
Measuring changes in nurses' sleep quality using the total score of the Petersburg Sleep Quality Questionnaire, with higher scores indicating more unfavorable sleep quality.
Timepoint
Questionnaires are completed before the start of the intervention and at the end of every 3 sessions per week(end of each week).
Method of measurement
The intervention will consist of 9 reflexology sessions, which will be performed for 3 weeks, 3 sessions per week for each participant. The sessions will be held at home or in a hospital room (as designated) by a previously trained person under the supervision of a relevant expert. Eachsession will last approximately 15-20 minutes. Data will be collected via an electronic questionnaire at the end of each week after 3 sessions.

Intervention groups

1

Description
After grouping and practical training for the intervention group in internal programs, a group of members is formed and an educational video is prepared. Before the start of each session, the video is uploaded and provided to them. Socks are prepared and the individuals wear them. The desired points are marked with a marker and given to the individual. At the end of each week, after 3 sessions (per week), an electronic questionnaire is provided to the participants and completed.
Category
Prevention

2

Description
Control group: Only the questionnaire is completed every week without any intervention.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
zahra sarlak
Street address
Qazvin street Farabi haospital
City
Tehran
Province
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Postal code
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology
Street address
Qazvin square Farabi Hospital
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person

Zahra Sarlak
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Tehran University of Medical Sciences
Full name of responsible person
Shokoh varaei
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Zahra Sarlak
Position
Nurse
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Other areas of specialty/work
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Fax
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sarlak.zahra32@gmail.com

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
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The dataset includes demographic characteristics, standardized stress and sleep quality scores, and reflexology intervention protocols. All data will be anonymized and extracted into Excel files, and IBM SPSS Statistics will be used for all statistical analyses.
When the data will become available and for how long
After the completion of the study, I will proceed with writing the article.
To whom data/document is available
All researchers and interested individuals will be able to access it.
Under which criteria data/document could be used
Data will be available for legitimate scientific research purposes only. Applicants must provide a research proposal demonstrating how the data will contribute to the understanding of nursing occupational health. Access will be granted upon approval by the Principal Investigator, contingent on a signed agreement to use the data strictly for non-commercial research and to maintain participant anonymity."
From where data/document is obtainable
"For data requests, researchers should contact the Principal Investigator (PI) directly via their official institutional email address."
What processes are involved for a request to access data/document
"Applicants must submit a written request including: 1) The research objective, 2) A brief summary of the proposed methodology, 3) A list of required variables,

and 4) Ethical clearance (if applicable) to the Principal Investigator's email. The request will be reviewed by the research team, and a decision will be communicated within 4 weeks, provided it aligns with ethical and scientific standards."

Comments