Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment the effect of self-foot reflexology massage on sleep quality in nurses

Protocol summary

Study aim
Determining the effect of foot reflexology massage on sleep quality in nurses

Design
Clinical trial with control group with parallel, randomized, on 86 nurses, four-way permutation blocking method was used for randomization.

Settings and conduct
The location of the project is the Intensive Care Unit (ICU), Cardiac Care Unit (CCU) and the Emergency Department of Vasei, Heshmatie and Emdad Hospitals. After obtaining written consent, nurses who are eligible to enter the study using random assignment to two groups of control (not receiving foot reflex massage) and intervention (after a training session, receiving foot reflex massage for 12 sessions) are divided. First, the demographic information form is completed by the nurses and also before the intervention and five days after the intervention, the Pittsburgh Sleep Quality Questionnaire will be completed.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Having a minimum age of 22 and a maximum of 60 years Willingness to collaborate in research Get a Pittsburgh questionnaire score greater than 5 Having healthy limbs Do not take sleeping pills No history of receiving reflective massage Exclusion Criteria: Suffering from psychological diseases Alcohol and drug addiction Having skin diseases Pregnancy and lactation

Intervention groups
In the intervention group, during a training session, the method of using reflective massage is taught and to ensure, they are asked to perform the intervention once in the presence of the researcher and then reflective massage two days a week for 6 weeks (12 sessions in total).) For 30 minutes (15 minutes for each leg) 30 minutes before bedtime. During this period, follow-up is done by phone to ensure accurate intervention. The control group will not receive any intervention during the study.

Main outcome variables
A sleep quality score based on the Pittsburgh Sleep Quality Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220222054100N1**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date
2022-03-02, 1400/12/11

Registrant information

Name
Mojgan Gholitabar

Name of organization / entity

Country
Iran (Islamic Republic of)

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gholitabaromranim98@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-11, 1400/12/20

Expected recruitment end date
2022-05-10, 1401/02/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of self-foot reflexology massage on sleep quality in nurses

Public title

Assessment the effect of self-foot reflexology massage on sleep quality in nurses

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a minimum age of 22 and a maximum of 60 years Willingness to collaborate in research Get a Pittsburgh questionnaire score greater than 5 Having healthy limbs Do not take sleeping pills No history of receiving reflective massage

Exclusion criteria:

Suffering from psychological diseases Alcohol and drug addiction Having skin diseases Pregnancy and lactation

Age

From **22 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by available methods and will be placed in intervention and control groups using random allocation permutation blocks. The randomization method in this study is based on quadratic blocks. These blocks consist of 2 letters (A and B). The letter A will be considered for the intervention group and the letter B for the control group. The blocks will be selected randomly and blindfolded. Each block determines the order of entry into the intervention and control groups. Thus, twenty-two quadruple blocks are formed and within each block, two people are considered as intervention people and two people as control people, and thus they will be placed in intervention and control groups. For example, assuming the ABAB block is selected from the left hand, the first and third samples will be included in the intervention group, respectively, and the second and fourth samples will be included in the control group, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar university of medical sciences

Street address

No. 31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

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Sabzevar

Province

Razavi Khorasan

Postal code

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Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.MEDSAB.REC.1400.163

Health conditions studied

1

Description of health condition studied

Sleep quality of nurses

ICD-10 code

F51.2

ICD-10 code description

A lack of synchrony between the sleep-wake schedule and the desired sleep-wake schedule for the individual's environment, resulting in a complaint of either insomnia or hypersomnia

Primary outcomes

1

Description

Percentage of people whose sleep quality score is between 5 and 21.

Timepoint

Measurement of sleep quality score at the beginning of the study (before the intervention) and five days after the end of the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Reflexology foot massage two days a week for 6 weeks (12 sessions in total) for 30 minutes (15 minutes for each leg) 30 minutes before bedtime, 5 minutes out of 15 minutes for general massage The sole of the foot and 10 minutes of massage are dedicated to the reflex points of the sole of the foot. In such a way that a constant and gentle pressure within the tolerance of each person with a slow speed and regular rhythm of 0.5 cm using the middle part of the first paragraph of the index and thumb fingers so that one third of the nail bed is white, in reflex points (point Apply to the pineal glands on the outside of the big toe, the point of the brain and the point of the solar plexus). The researcher has been taught the method of using reflective massage and the skill of performing massage and applying pressure in the desired location, and to ensure this, they are asked to perform the intervention once in the presence of the researcher.

Category

Treatment - Other

2

Description

Control group: The control group does not receive any intervention during the study and only during the study they are controlled and followed in terms of exclusion criteria and so on. Then, five days after the intervention, the Pittsburgh Sleep Quality Questionnaire will be completed by both groups and the sleep scores of the control and intervention groups will be determined.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Hospital

Full name of responsible person

Mojgan Gholitabar

Street address

Vasei Hospital, Tohid Shahr Blvd, Sabzevar

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2

Recruitment center

Name of recruitment center

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3

Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

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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
Sabzevar 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
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Position
Master student of Internal Surgery Nursing
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available