Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the Effect of Simple Massage and Foot Reflexology Massage on Fatigue and Impacts of Fatigue among Female Nurses.

Protocol summary

Study aim
Comparing the Effect of Simple Massage with Foot Reflexology Massage on Fatigue

Design
The clinical trial has a control and intervention group with a sample size of 30 nurses in each group. The samples will be allocated with stratified block method, which the selection of each block will be done through random allocation 2 software.

Settings and conduct
After sampling, foot reflexology massage in intervention group and simple massage in control group will be done by researcher for 20 minutes in 3 consecutive days. In both groups, fatigue and impacts of fatigue will be measured by Chalder fatigue scale and fatigue impact scale before the massage, after 3 sessions massage and 1 week later and at last 2 groups are compared. The place of study is Buali Hospital in Sari. Blinding was not done.

Participants/Inclusion and exclusion criteria
Inclusion criteria include Consent to participate in the study, Being female, Nurses with fatigue of at least 22 according to the Chalder Fatigue Scale, Employment for at least one year in one of the hospital departments, Not suffering from a chronic, debilitating or incurable disease such as Cancer/Blood Pressure/Diabetes, Not suffering from neurological ,Not having severe neuropathy .Exclusion criteria include failure to complete the questionnaire or incomplete completion, incomplete participation in massage sessions and failure to follow the massage program for any reason for one session, and withdrawal from further participation in the research.

Intervention groups
For the intervention group, the reflexology massage technique is used. For the control group, simple massage without stimulating the reflex points is used.

Main outcome variables
Fatigue, Impacts of Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171203037723N7**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**

Registration date
2023-07-29, 1402/05/07

Registrant information

Name
Hamideh Azimi Lolaty

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 7343

Email address
azimihamideh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-20, 1402/02/30

Expected recruitment end date
2023-08-21, 1402/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the Effect of Simple Massage and Foot Reflexology Massage on Fatigue and Impacts of Fatigue among Female Nurses.

Public title
Comparing the Effect of Simple Massage and Foot Reflexology Massage on Fatigue and Impacts of Fatigue

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study. Being female. Nurse`s fatigue at least 22 according to the Chalder Fatigue Scale. At least one year has passed since the Working in one of the hospital departments. Not having a second job, either working in another hospital or working in a profession other than nursing Not recieving any other massage therapy plan. Not drinking tea or coffee one hour before massage. Not suffering from a chronic, debilitating or incurable disease such as Cancer, Hypertension and Diabet. Not suffering from neurological and mental disease and getting score of less than 3.5 based on general public health scale. Not suffering from severe neuropathy such as lumbar disc and multiple sclerosis(MS) . Not having any kind of sores or blisters on the feet.

Exclusion criteria:
Reluctance to participate in the study. Suffering from cancer, diabetes or hypertension. Suffering from neurological or mental disease. Suffering from severe neuropathy such as lumbar disc or multiple sclerosis(MS).

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
A nurse working in one of the departments of Bu Ali Hospital

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be selected based on the available sampling and inclusion criteria and. then they will be randomly divided into intervention and control groups. The samples will be allocated with stratified block randomization. Blocks will be matched according the age. For this purpose, 15 blocks of four will be considered. Block type selection will be done through random allocation 2 software. Code A means intervention group and code B means control group. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. As each patient enters, the envelopes will be opened and the treatment will be applied.

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 Mazandaran University of Medical Sciences

Street address
Student Research Department, Moallem St., Sari

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2023-06-10, 1402/03/20

Ethics committee reference number
IR.MAZUMS.REC.1402.112

Health conditions studied

1

Description of health condition studied
fatigue

ICD-10 code
R53

ICD-10 code description
Malaise and fatigue

Primary outcomes

1

Description
Fatigue score in Chalder questionnaire

Timepoint
Before and immediatly after intervention

Method of measurement
Chalder Fatigue Scale

2

Description
Fatigue effects score in Fisk questionnaire

Timepoint
Before and immediatly after intervention

Method of measurement
Fisk Fatigue Impact Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Each of the nurses will be placed in the rest room and after washing and drying their feet, they will lie on the examination bed and the sole reflex massage protocol will be applied. The researcher will hold the foot with one hand. And by pressing on the sole of the foot, bend and straighten it from the wrist, then apply direct pressure on the three points of the pituitary gland, kidney and solar plexus with the thumb and it is done in a circular manner with the applied pressure. Each point will be 3 minutes, 9 + 1 sets equal to 10 minutes for each leg, a total of 20 minutes for two legs reflex massage.
Category
Other

2

Description
Control group: Each of the nurses will be placed in the rest room and after washing and drying the feet, they will lie on the examination bed and a simple massage protocol without stimulating reflex points will be applied. The researcher will use the soles and fingers. The thumb is done by applying short pressure in a circular manner, starting from the heel to the fingers.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali Sina Hospital
Full name of responsible person
Hamideh Azimi Lolaty
Street address
Bu Ali Sina Hospital, Imam Sq., Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3334 1030
Email
azimihamideh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hamideh Azimi Lolaty
Street address
Nasibeh School of Nursing and Midwifery, Vesal-e-Shirazi Ave., Amir Mazandarani, Blvd
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3336 7343
Email
azimihamideh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mazandaran University of Medical Siences
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
Mazandaran University of Medical Sciences
Full name of responsible person
Hamideh Azimi Lolaty
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nasibeh School of Nursing and Midwifery, Vesal-e-Shirazi Ave, Amir Mazandarani Blvd
City
Sari
Province
Mazandaran
Postal code

4815733971

Phone

+98 11 3336 7343

Email

azimihamideh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Azimi Lolaty

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nasibeh School of Nursing and Midwifery, Vesal-e-Shirazi Ave, Amir Mazandarani Blvd

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3336 7343

Email

azimihamideh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Azimi Lolaty

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nasibeh School of Nursing and Midwifery, Vesal-e-Shirazi Ave., Amir Mazandarani, Blvd

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3336 7343

Email

hamidehazimi@gmail.com

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

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