Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology massage on burn specific pain anxiety and sleep condition of patients hospitalized to the burn intensive care unit

Protocol summary

Study aim

Determining The effect of foot reflexology massage on burn specific pain anxiety and sleep condition of patients hospitalized to the burn intensive care unit

Design

52 patients randomly assigned randomly into two groups of 26 massage and control groups based on computer program and Block Randomization.

Settings and conduct

After sampling, foot reflexology massage is performed for the intervention group for 20 minutes in three consecutive days. Then after 15 minutes after dressing, the BSPAS questionnaire is filled in from the third day of hospitalization in the department for 3 days. In the control group, the BSPAS questionnaire was filled out by the researcher immediately before dressing and 15 minutes later. In both groups, the sleep status of the last 24 hours on the third to sixth days before going to dressing is measured based on the hospital sleep questionnaire. The location of the study is Zare Hospital of Sari.

Participants/Inclusion and exclusion criteria

Criteria for entering: 18-65 years old patients , conscious with unintentional, acute burns, moderate and severe burns, and able to communicate with the assessor, 48 hours after admission, no history of mental illness, especially severe anxiety , severe neuropathy, cognitive impairment, and not be addicted to drugs; lack of underlying diseases such as hypothyroidism and illnesses such as rheumatology. not repeatable history of hospitalization, non-burning of the ankle, lack of respiratory distress and no intubation Exit criteria: Intubation of the patient during follow-up, the change in the color of the wound due to infection (according to the positive wound healing), the discharge or death of the patient and the patient's refusal to continue cooperation

Intervention groups

Intervention for the massage group.

Main outcome variables

burn specific pain anxiety and sleep condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N27**
Registration date: **2018-08-18, 1397/05/27**
Registration timing: **prospective**

Last update: **2018-08-18, 1397/05/27**
Update count: **0**

Registration date

2018-08-18, 1397/05/27

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of foot reflexology massage on burn specific pain anxiety and sleep condition of patients hospitalized to the burn intensive care unit

Public title
The effect of foot reflexology massage on burn specific pain anxiety and sleep condition of patients hospitalized to the burn intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
18-65 years old patients, conscious with unintentional, acute burns, moderate and severe burns and able to speak or communicate with the assessor, 48 hours after admission, no history of mental illness, especially severe anxiety, severe neuropathy, such as diabetes, cognitive impairment, and the ability to communicate and hear and not be addicted to drugs; lack of underlying diseases such as hypothyroidism and illnesses such as rheumatology, etc. no repeatable history of hospitalization due to burn, non-burning of the ankle, lack of respiratory distress and no intubation

Exclusion criteria:
Intubation of the patient during follow-up, the change in the color of the wound due to infection (According to the positive wound healing), the discharge or death of the patient and the patient's refusal to continue cooperation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
52 patients were randomly assigned into two groups of massage and control with equal number based on computer program and Block Randomization.

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
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City
Sari

Province
Mazandaran

Postal code
4816715793

Approval date
2018-08-05, 1397/05/14

Ethics committee reference number
IR.MAZUMS.REC.97-1679

Health conditions studied

1

Description of health condition studied
Burn specific pain anxiety and sleep condition

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The effect of foot reflexology massage on burn specific pain anxiety and sleep condition

Timepoint
From the third day of admission immediately before massage (for the massage group) and immediately before dressing (for the control group) and 15 minutes later for 3 consecutive days

Method of measurement
BSPAS questionnaire

2

Description
The effect of foot reflexology massage on sleep condition

Timepoint
Determining the sleep status of the last 24 hours on days 3 to 6, before admission to dressing for both groups (test and control)

Method of measurement
SNHSQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Foot reflexology massage will be done for 20 minutes (10 minutes per foot) before dressing on days 3 to 5, using baby oil, manufactured by Firuz, with the number (ISO 9001 ISO 14001 OHSAS 18001).
Category
Lifestyle

2

Description
Control group: Do not get any massage.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Zare Accidents and burns Hospital of Sari
Full name of responsible person
Reza Alinia
Street address
Guibar tree way, Mazandaran University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
College Student Research Committee
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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 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Masoumeh Bagheri Nasami
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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
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