Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology massage on pain, anxiety and sleep quality after bone marrow sampling in leukemia patients

Protocol summary

Study aim
Determining the effect of foot reflexology massage on pain, anxiety and sleep quality after bone marrow sampling in leukemia patients

Design
A double-blind clinical trial has an intervention group and a control group, which are parallel. Allocation of samples is done randomly by permutation blocks method and the total number of samples is equal to 74. Random Allocation software was used for randomization

Settings and conduct
Research environment: Oncology department of Namazi and Amir Hospital located in Shiraz city and collecting data related to the intensity of pain and anxiety before the intervention of foot reflexology massage with almond oil and in the evening of the first to third day after the intervention at 9:00 and 17:00 and sleep quality before intervention and in the morning of the first to third day after the intervention at 9 am Blinding: The data collector and data analyst will be unaware of the sample allocation until the end of the work.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidacy of patients aged 18 to 60 years for bone marrow sampling according to the Doctor's diagnosis and Patients' Satisfaction with participating in the research project Exclusion criteria: Unwillingness to stay in the study and Occurrence of sudden complications after bone marrow sampling such as Shock, Severe bleeding

Intervention groups
the intervention group, the researcher first rubs his hands together to warm both hands and a pillow will be placed under the patient's head and feet, and with the use of sweet almond oil, he will be subjected to a warming step and then a foot reflexology massage. Reflexive foot massage for patients will be performed for twenty minutes on both feet in six sessions and during three days and twice every day, and in the control group, only massage with almond oil will be performed to warm

Main outcome variables
pain anxiety sleep quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241101063561N1**
Registration date: **2024-11-21, 1403/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-21, 1403/09/01**
Update count: **0**

Registration date
2024-11-21, 1403/09/01

Registrant information
Name
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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-11-20, 1403/08/30
Expected recruitment end date
2025-01-19, 1403/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology massage on pain, anxiety and sleep quality after bone marrow sampling in leukemia patients

Public title
Effect of foot reflex massage in leukemia patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The age of the patients should be between 18 and 60 years 2. The patient's candidacy for bone marrow sampling according to the doctor's diagnosis 3. The ability to tolerate the sole reflex massage technique 4. Not having a history of known mental illness that is treated with anti-anxiety and sedative drugs before the intervention. 5. Patients' satisfaction with participating in the research project

Exclusion criteria:
Reluctance to stay in the study 2. Occurrence of sudden complications after bone marrow sampling, such as shock, severe bleeding.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
By using the random allocation method with the replacement block method, people are divided into two control and intervention groups. For this purpose, using random block generation software on the Internet, 19 random blocks of 4 are formed. The content of each block is placed in a sealed envelope. After choosing the desired person, the envelopes are opened in order and based on the envelope, they are assigned to one of the intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the person doing the data collection and the person doing the analyzes were blinded to the groups until the end of the work.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information s

Street address
Hazrat Fatemeh College of Nursing and Midwifery, Entrance to Namazi Hospital, Namazi Square, Shiraz, Fars Province

City
shiraz

Province
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Postal code
7193613119

Approval date
2024-10-05, 1403/07/14

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1403.076

Health conditions studied

1

Description of health condition studied
Bone marrow sampling in patients with leukemia

ICD-10 code
C95

ICD-10 code description
Leukemia of unspecified cell type

Primary outcomes

1

Description
PAIN

Timepoint
The time of data collection is related to pain intensity before the intervention and in the evening of the first, second and third days after the intervention at 9:00 and 17:00.

Method of measurement
PAIN VISUAL SCALE

2

Description
ANXIETY

Timepoint
The time of data collection is related to pain intensity before the intervention and in the evening of the first, second and third days after the intervention at 9:00 and 17:00.

Method of measurement
Spielberger Situational Anxiety Questionnaire

3

Description
sleep quality
Timepoint
Sleep quality before the intervention and in the morning of the first, second and third day after the intervention at 9 am and their information will be recorded by the researcher or assistant researcher.
Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patient will lie down on the bed in a quiet place. The researcher will perform reflexology for twenty minutes. The reflexology method includes preparation, heating and stimulation and massage techniques. First, the researcher rubs his hands together to warm both hands, and secondly, he warms the patient's feet by rubbing them with sweet almond oil. turning outwards and inwards and movements in the heels. When the foot is warmed up enough, the massage will be done using the fingers and applying pressure of about 0.5 cm. The researcher applies pressure on the thumb and solar plexus, the inner and outer edge of the foot, the inner edge of the sole of the foot, and the wrist, which are related to the quality of sleep, fatigue, back pain, shoulder pain, hands and feet, respectively. In reflexology, the big toe, medial edge, top and base of the big toe will be stimulated. The inner edge of the leg corresponding to the cervical spine, chest, lumbar spine and sacrum will also be stimulated. Reflex points on the outer edge of the leg, such as the feet, knees, lower back, elbows, arms and shoulders, will also be stimulated. Reflexology will also be done on the inner edge of the foot, the sole of the foot, and the heel of the ankle, which will stimulate the sciatic nerve and the lower back. Reflexology may have side effects such as leg swelling, frequent urination, defecation and fatigue. Foot reflex massage intervention will be performed by the researcher in six sessions and for twenty minutes for each leg in three days and twice a day. Data collection is related to pain intensity before the intervention and in the evening of the first, second and third days after the intervention at 9:00 and 17:00. The patient's anxiety before the intervention and in the evening of the first, second and third days after the intervention is at 9:00 and 17:00 and the quality of sleep is at 9:00 a.m. before the intervention and in the morning of the first, second and third day after the intervention. They will be recorded by the researcher or research assistant
Category
Other

2

Description
Control group: In the control group, they will only receive massage with almond oil to warm their feet and the main massage stage will not be performed for them, and the level of pain before the intervention and twice daily in the morning and evening, the level of anxiety before the intervention and twice daily in the morning And the evening and the amount of sleep quality of the patients will be measured and recorded before the intervention and every morning
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Khatereh Rostami
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Deputy of Research and Technology, Seventh Floor, The Central Building of Shiraz University of Medical Sciences, Shiraz, Fars Province
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Khatereh Rostami
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
After the end of the study, it is possible to share the data
When the data will become available and for how long
After the end of the study, it is possible to share data for one year
To whom data/document is available
Researchers working in academic and scientific institutions of medical sciences
Under which criteria data/document could be used
Analysis on documents and data is allowed
From where data/document is obtainable
Mrs. Dr. Khatereh Rostami is responsible for this project. Phone Number: +98 71 3647 4254 Address: Hazrat Fatemeh College of Nursing and Midwifery, Entrance to Namazi Hospital, Namazi Square, Shiraz, Fars Province Email: khatereh.rostami.nursing@gmail.com
What processes are involved for a request to access data/document
In order to access the information of the study, first of all, contact should be made with the manager of this project, Dr. Khatereh Rostami, whose profile is attached below, and then after reviewing the relevant request and meeting the requirements, the documents will be sent as soon as possible. Phone: +98 71 3647 4254 Address: Fars Province, Shiraz, Namazi Square, the entrance of Namazi Hospital, Hazrat Fatima College of Nursing and Midwifery Email: khatereh.rostami.nursing@gmail.com
Comments