Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

comparison of the foot reflexology massage with placebo on fatigue, pain intensity and sleep quality in patients with lymphoma referring to Shiraz University of Medical Sciences: a clinical trial study

Protocol summary

Study aim
The comparison of foot reflexology massage with placebo on fatigue, pain intensity and sleep quality in lymphoma patients referring to Shiraz University of Medical Sciences

Design
A clinical trial with control group, parallel group randomized trial and single blinded

Settings and conduct
the settings of the study would be all Hematology and Oncology wards in Namazi and Amir Hospital affiliated to Shiraz University of Medical Sciences. In this study, a person who collects the outcomes of the study, as well as a statistician and health care provider, will be blind until the end of the study and completion of the data analysis and reporting.

Participants/Inclusion and exclusion criteria
The inclusion criteria were lymphoma patients with 18 years old or above, and speak Persian language. The patients with infectious or bleeding ulcer in their legs, inability to tolerate foot reflexology massage; physical disability, or known case of psychiatric disorder that are disable to perform self-care; and the use of sleep medications would be excluded.

Intervention groups
The patient lays on a bed in a quiet environment. The massage therapist places at the below of the patient's bed and each foot receives a reflective massage for 15 minutes. Firstly, the sweet almond oil is used. Then, the following points would be massaged for five consecutive days: the sleep points consisted of the thumb and Solar Plexus. Moreover, the inner edge, soles and heel to the ankle of the foot which relate to the fatigue and pain of the spine, the scapula, the hands, and the legs, would be massaged. Patients in the control group do not receive any type of massage during these 5 days and receive the same care that is provided to the intervention group.

Main outcome variables
fatigue; pain intensity; sleep quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130616013690N6**
Registration date: **2018-09-28, 1397/07/06**
Registration timing: **prospective**

Last update: **2019-01-24, 1397/11/04**
Update count: **1**

Registration date
2018-09-28, 1397/07/06

Registrant information

Name
Masoume Rambod

Name of organization / entity
Shiraz University of Medical Science

Country
Iran (Islamic Republic of)

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+98 71 1647 4258

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rambodm@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-29, 1397/07/07

Expected recruitment end date
2018-12-28, 1397/10/07

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison of the foot reflexology massage with placebo on fatigue, pain intensity and sleep quality in patients with lymphoma referring to Shiraz University of Medical Sciences: a clinical trial study

Public title
Effect of foot reflexology massage on lymphoma patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of lymphoma according to patient records Patients with 18 years old or above be able to understand and speak in Persian language Interested in participating in the study
Exclusion criteria:
Infectious or bleeding ulcers in the legs Intolerance of reflective massage Physical disability or known mental disorder that disable the patient in self-care The use of sleep medications
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Firstly, the patients are included in the study using convenience sampling. Then, a random block with four block is used to randomly assign patients into the both groups. Block list is provided by the "Create a block randomization list" software. Each block is then placed inside a envelope and numbered. In this way, after selecting a patient, a numbered envelope is opened, the patient is allocated into the intervention or control groups based on the contents of envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the person who evaluates the outcome, the healthcare staff , and the statistician would be remained blind into the groups. For this purpose, all of the above individuals would be blind into the groups until the analysis of the data is complete and reported.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Shiraz University of Medical Sciences
Street address
Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Approval date
2018-06-20, 1397/03/30
Ethics committee reference number
IR.SUMS.REC.1397.267

Health conditions studied

1

Description of health condition studied
Hodgkin lymphoma
ICD-10 code
C81
ICD-10 code description
Hodgkin lymphoma

2

Description of health condition studied
Non-Hodgkin lymphoma
ICD-10 code
C85.9
ICD-10 code description
Non-Hodgkin lymphoma, unspecified

Primary outcomes

1

Description
Fatigue
Timepoint
Before the intervention and fifth days of the intervention
Method of measurement
Multidimensional Fatigue Inventory

Secondary outcomes

1

Description
Pain intensity
Timepoint
Before the intervention and fifth days of the intervention
Method of measurement
numerical pain scale

2

Description
sleep quality
Timepoint
Before the intervention and fifth days of the intervention
Method of measurement
Petersburg Sleep Questionnaire

Intervention groups

1

Description
Intervention group: The patient lays on a bed in a quiet environment. The massage therapist places at the below of the patient's foot and each foot receives a reflective massage for 15 minutes. Massage will be done in five consecutive days at 4 pm. In order to do massage, firstly, the sweet almond oil is used. Then the foot thumb and Solar Plexus which are related to sleep receive massage. Moreover, the inner edge, solar, and heel to the ankle of the foot, which are related to fatigue and back, scapula, hands and feet pain are given massage for five consecutive days.
Category
Rehabilitation

2

Description
Control group: The control group does not receive any type of massage. This group receives routine care such as the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi and Amir Hospital
Full name of responsible person
Masoume Rambod
Street address
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Basir Hashemi
Street address
f Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
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Shiraz
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Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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
Masoume Rambod
Position
Assistant Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
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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
No - There is not a plan to make this available
Title and more details about the data/document
main outcome
When the data will become available and for how long
2020
To whom data/document is available
University institutes
Under which criteria data/document could be used
The data can only be accessed by the journal that want to publish the article and no further use is permitted.
From where data/document is obtainable
In order to access to the data, contact to Email: rambodma@yahoo.com
What processes are involved for a request to access data/document
In order to access to the data, contact to Email: rambodma@yahoo.com
Comments