Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect and Comparison of Progressive Muscle Relaxation and foot reflexology on sleep quality in cancer patients undergoing chemotherapy

Protocol summary

Study aim
Comparison and determine the effect of progressive Muscle relaxation and foot reflexology on sleep quality in cancer patients undergoing chemotherapy

Design
The study is a single-blind randomized clinical trial. the sample size is 150 cancer patients.

Settings and conduct
Intervention is the study of sleep quality will conduct for 4 weeks onto cancer patients in Imam Reza hospital in Kermanshah-Iran.Patients will perform relaxation two time daily, each time 20 minutes and foot reflexology massage will be done for thirty minutes (every foot fifteen minutes) and the control group will receive routine care. the Study is single-blinded.The data analyst will not be aware of the categorization of the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Consent to participate in the study , Complete consciousness , score equal or more than five from the Pittsburgh quality of sleep questionnaire , ability of verbal communication, undergoing chemotherapy based on treatment protocols, lasting at least one month of chemotherapy history, doing at least two chemotherapy sessions, Not having skin wound,Infection and skin disease. Exclusion criteria : having coagulation disorder (due to the possibility of producing clots and thromboembolism), no tolerance of the massage, use of other complementary therapies for improving the sleep.

Intervention groups
Progressive muscle relaxation group: Patients performed relaxation for 4 weeks, two time, daily, each time for 20 minutes, preferably once before bedtime. Foot reflexology massage group: Massage therapy is performed once a day, preferably before the patient's of sleeping for 4 weeks, each session of foot reflexology massage will last thirty minutes (every foot fifteen minutes) . Control group: The control group will receive routine care.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170619034641N4**
Registration date: **2018-07-27, 1397/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**
Update count: **0**

Registration date
2018-07-27, 1397/05/05

Registrant information

Name
Alireza Abdi

Name of organization / entity
nursing and midwifery school, Kermanshah university of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 3725 0111

Email address
arabdi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-11-21, 1397/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect and Comparison of Progressive Muscle Relaxation and foot reflexology on sleep quality in cancer patients undergoing chemotherapy

Public title
The effect of muscle relaxation and foot reflexology massage on sleep of cancer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study. Complete consciousness. score equal or more than five from the Pittsburgh quality of sleep questionnaire ability of verbal communication undergoing chemotherapy based on treatment protocols. lasting at least one month of chemotherapy history doing at least two chemotherapy sessions. Not having skin wound,Infection and skin disease.
Exclusion criteria:
Having coagulation disorder (due to the possibility of producing clots and thromboembolism). No tolerance of the massage. Use of other complementary therapies for improving the sleep
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 150 patients with inclusion criteria were randomly assigned into three groups in a randomized, randomized manner. for random allocation, we will chose three types of Cart with similar colors, and write the numbers of 1 to 3 upon them. one hundred and fifty carts will put inside a glass container the number 1 is related to progressive muscle relaxation group and card number 2 the reflexology massage group and card number 3 the control group. one cart will be allocated to any individual and he/she is placed in the relevant group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyst does not know the categorization of the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran
City
Kermanshah
Province
Kermanshah
Postal code
69531-13433
Approval date
2018-05-22, 1397/03/01
Ethics committee reference number
IR.KUMS.REC.1397.135

Health conditions studied

1

Description of health condition studied
sleep quality
ICD-10 code
F51.8
ICD-10 code description
Other sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
sleep quality
Timepoint
At the beginning of the study and Four weeks after the intervention
Method of measurement
Pittsburgh sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First intervention group: Progressive muscle relaxation:Patients perform practice relaxation for 4 weeks, two time, daily, each time lasts 20 minutes, preferably once will perform before bedtime.

Category
Rehabilitation

2

Description
Intervention group: Second intervention group: Foot reflexology massage: Massage is performed once a day, preferably before sleep for 4 weeks. each session lasts thirty minutes (each foot fifteen minutes). Five minutes of fifteen minutes is related to general foot massage on the soles of the foot and ten minutes of massage related to the Pineal gland point in the outer part of the foot thumb. Massage is done slowly, with regular rhythm and depth that is tolerable to the patient.

Category
Rehabilitation

3

Description
Control group: The control group will receive routine care.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospitals of Kermanshah

Full name of responsible person
Alireza AAbdi

Street address
Kermanshah University of Medical Sciences, Kermanshah, Shahid Beheshti Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
69531-13433

Phone
+98 83 3827 9394

Fax
+98 83 3827 9899

Email
ArAbdi@kums.ac.ir

Web page address
http://5.63.15.58/webdocument/load.action?webdocument_code=8000&masterCode=3002995

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Alireza abdi

Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Boulevard, Kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
69531-13433

Phone
+98 83 3827 9394

Fax
+98 83 3827 9899

Email
A_abdi61@yahoo.com

Web page address
http://5.63.15.58/webdocument/load.action?webdocument_code=8000&masterCode=3002995

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Alireza Abdi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Boulevard, Kermanshah

City
Kermanshah
Province
Kermanshah
Postal code
69531-13433
Phone
+98 83 3827 9394
Fax
+98 83 3827 9899
Email
Arabdi@kums.ac.ir
Web page address
http://5.63.15.58/webdocument/load.action?webdocument_code=8000&masterCode=3002995

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
alireza abdi
Position
PhD in Nursing Education-Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blvd. Kermanshah
City
kermanshah
Province
Kermanshah
Postal code
69531-13433
Phone
+98 83 3827 9394
Fax
+98 83 3827 9899
Email
Arabdi@kums.ac.ir
Web page address
http://5.63.15.58/webdocument/load.action?webdocument_code=8000&masterCode=3002995

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
alireza abdi
Position
PhD in Nursing Education-Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blvd. Kermanshah
City
kermanshah
Province
Kermanshah
Postal code
69531-13433
Phone
+98 83 3827 9394
Fax
+98 83 3827 9899
Email
A_abdi61@yahoo.com
Web page address
http://5.63.15.58/webdocument/load.action?webdocument_code=8000&masterCode=3002995

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
we share the SPSS data file, questioners and final reports
When the data will become available and for how long
at the final step of the project after publishing the article
To whom data/document is available
the journal editors, researchers
Under which criteria data/document could be used
the researcher have an academic email and link
From where data/document is obtainable
sending a request to the corresponding author
What processes are involved for a request to access data/document
after requisting, the data will send during one week
Comments
no applicable