

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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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 times, 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

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Kermanshah University of Medical Sciences,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

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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

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 requesting, the data will send during one week

Comments

no applicable