Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of reflexology on fatigue in cancer patients receiving chemotherapy in Tohid Hospital in Sanandaj, 2016

Protocol summary

Summary

(1)Objectives: The aim of this study to determine the effect of reflexology on fatigue in patients with cancer receiving chemotherapy. (2) Design: This study is a clinical trial with random allocation and would be done in phase 2-3 clinical trials. The study population of cancer patients undergoing chemotherapy in the oncology and chemotherapy departments of Tohid Hospital in Sanandaj. (3) Setting and conduct: The likelihood of sample loss and based on inclusion criteria 80 participants will be divided in two groups: intervention and control. Before intervention,fatigue in both intervention and control groups are measured by FSS questionnaire that patients's fatigue measures with 9 items, each of which has a rating of 1-7 on a Likert scale. For patients in the intervention group, after preparing the patient and lubricate the soles of the feet by sweet Almond oil taht In terms of coldness and wet applications For all temperaments, in four consecutive days, each day for 30 minutes massage contains 10 minute relaxation massage and 20 minutes massage therapy on the soles of both feet reflexology done. During this period, ther is not any intervention for control group and Only usual care both for them and for the study group done. (4) Participants including major eligibility criteria: Inclusion criteria for patients include: Cancer patients undergoing chemotherapy; volunteered to participate in the study; no history of any underlying disease or condition affecting fatigue(Cardiovascular and respiratory diseases and mental illness); stable health; no history of complementary medicine (Acupressure, Reflexology); after a round of chemotherapy; without any sort of injury in the foot and having age between 18 to 65 years. And exclusion criteria were: not wanting to continue participating in the study for any reason; creating an unusual situation for the patient and change in his health condition. (5) Intervention: Intervention for the study group is Reflexology and reflexology based on the idea that energy flow in the body From feet to head is stimulate and make peace.Foot reflexology massage classified as a mental and physical action that can improve general fatigue. (6) main outcome measures: Our main outcome variable is fatigue that measur with FSS questionnaire . .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021232518N1**
Registration date: **2017-03-15, 1395/12/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-15, 1395/12/25

Registrant information

Name

Mahin Hesami

Name of organization / entity

Kurdistan University of Medicai Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

Expected recruitment start date

2017-03-11, 1395/12/21

Expected recruitment end date

2017-10-13, 1396/07/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of reflexology on fatigue in cancer patients receiving chemotherapy in Tohid Hospital in Sanandaj, 2016

Public title
The effect of reflexology on fatigue in cancer patients receiving chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria for patients include: Cancer patients undergoing chemotherapy; volunteered to participate in the study; no history of any underlying disease or condition affecting fatigue(Cardiovascular and respiratory diseases and mental illness); stable health; no history of complementary medicine(Acupressure, Reflexology); after a round of chemotherapy; without any sort of injury in the foot and having age between 18 to 65 years. exclusion criteria were: not wanting to continue participating in the study for any reason; creating an unusual situation for the patient and change in his health condition.

Age
From **17 years** old to **64 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Kurdistan University of Medicai Sciences

Street address
Kurdistan University of Medicai Sciences , Pasdaran street, Sanandaj

City
Sanandaj

Postal code
6617713446

Approval date
2017-02-13, 1395/11/25

Ethics committee reference number
IR.MUK.REC.1395/334

Health conditions studied

1

Description of health condition studied
Cancer

ICD-10 code
C00-C97

ICD-10 code description
Malignant neoplasms

Primary outcomes

1

Description
Fatigue

Timepoint
Before and after 4 sessions of reflexology in 4 days consecutive

Method of measurement
FSS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For patients in intervention group, 4 session in 4 days foot reflexology is performed. reflexology foot based on the idea that energy flow in the body from feet to head is stimulate and make peace.Foot Reflexology massage classified as a mental and physical action that can improve general fatigue. For this group after preparing the patient and lubricate the soles of the feet by sweet Almond oil taht In terms of coldness and wet applications for all temperaments, reflexology is done. Reflexology in each session for 30 minutes contains 10 minute relaxation massage and 20 minutes massage therapy on the soles of both feet is performed.

Category
Rehabilitation

2

Description
control group:Without intervention. (no action is taken to control group).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital of Sanandaj, Oncology and Chemotherapy departmentsl
Full name of responsible person
Mahin Hesami
Street address
Kurdistan University of Medicai Sciences, Pasdaran street, Sanandaj
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kurdistan University of Medical Sciences
Full name of responsible person
Dr.Rezaei
Street address
Kurdistan University of Medicai Sciences, Pasdaran street, Sanandaj
City
Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kurdistan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kurdistan University of Medical Sciences, School of Nursing and Midwifery
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Mahin Hesami
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty