

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of foot reflexology on anorexia and quality of sleep in patients undergoing chemotherapy: a randomized clinical trial

Protocol summary

Study aim

Determine the effect of foot reflexology on anorexia and quality of sleep in patients undergoing chemotherapy

Design

Clinical trial with control group, Blind, randomized, with 60 patients

Settings and conduct

In this study will be selected 60 patients suffering from cancer hospitalized in the hematology and oncology departments of Ayatollah Khansari hospital in arak city and with random blocks will be divided to two groups of experimental and control. In the intervention group, patients takes 8 reflexology sessions twice a week for 4 weeks. Each session is 15 minutes massage for each leg, control group during this period twice a week for 4 weeks, upper surface of each leg 15 minutes without pressure will be touched. The questionnaires before and after 30 days will be completed for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a) age between 30-60 years old; b) being chemotherapy for at least one period; c) stages 2,3 or 4 of cancer. Exclusion criteria: a) Lack of Literacy; b) Non-treatable cancer.

Intervention groups

In the intervention group, patients takes 8 reflexology sessions twice a week for 4 weeks. Each session is 15 minutes massage for each leg, and includes 5 minutes for general massage of the foot and 10 minutes for massage on the pituitary gland, hypothalamus, pineal gland on the finger foot thumb and gastrointestinal tract (stomach, liver, small intestine). In the control group, patients do not receive any reflexology intervention and for unify the interventions, twice a week for 4 weeks, upper surface of each leg 15 minutes without pressure will be touched.

Main outcome variables

Sleep quality; anorexia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N8**

Registration date: **2019-08-27, 1398/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-27, 1398/06/05**

Update count: **0**

Registration date

2019-08-27, 1398/06/05

Registrant information

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on anorexia and quality of sleep in patients undergoing chemotherapy: a randomized clinical trial

Public title

The effect of foot reflexology on anorexia and quality of sleep in patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30-60 years old Experience of at least one period of chemotherapy Absence of psychological or known cognitive disease Stages 2,3 & 4 of cancer

Exclusion criteria:

Lack of literacy Non-treatable cancer The presence of deformity burn or ulcer in the areas of massage on the palms of the feet Use of hypnotic and sedative drugs Use of other complementary and alternative methods during the study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be by using random blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals with entry criteria are divided into intervention and control groups according to the random numbers table. One of the groups is A and the other is called B. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the Classification of the groups. Data analysis is also done by someone who is unaware of the allocation of groups. The control group also receive similar (but not effective) intervention so are unaware of the allocation to the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

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Province

Markazi

Postal code

38481-76941

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.ARAKMU.REC.1398.095

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C80

ICD-10 code description

Malignant neoplasm without specification of site

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before and 30 days after the intervention

Method of measurement

SMHSQ Sleep Quality Questionnaire

2

Description

Anorexia

Timepoint

Before and 30 days after the intervention

Method of measurement

Anorexia questionnaire with Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients takes 8 reflexology sessions twice a week for 4 weeks.

Category

Other

2

Description

Control group: in the control group, patients do not receive any reflexology intervention and for unify the interventions, twice a week for 4 weeks, upper surface of each leg 15 minutes without pressure will be touched.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khansari hospital, Arak

Full name of responsible person

Mehdi Harorani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mehdi Harorani

Position

Academic Instructor

Latest degree

Master

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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available