

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Foot Reflexology on The Quality of Sleep in Cancer Patients Selected Hospital at Shahid Beheshti University of Medical Sciences

Protocol summary

Study aim

The Effect of Foot Reflexology on The Quality of Sleep in Cancer Patients Selected Hospital

Design

Two arm parallel group randomised trial nonblinded preoperative then postoperative care and outcome assessment

Settings and conduct

Initially, using patient files in the chemotherapy department, evaluated the patients who first completed their chemotherapy and considered the criteria for entering the study. Then, the qualified samples will be taken after explaining the goals of the study, the importance of the research and the process of the study, written consent and informed consent. After considering the criteria for entry and non entry, among the samples of this study, 60 patients with pancreatic cancer are selected. patients with a sleep score of 5 and above of the Pittsburgh questionnaire were isolated and the research samples were randomly assigned to women and men by using numbering records and then selecting paired numbers. the test group and the individual numbers will be selected as the control group

Participants/Inclusion and exclusion criteria

inclusion criterion for research Patients with primary colorectal cancer Patient admitted to chemotherapy for the first time Earn score 5 and above Pittsburgh Sleep Quality Index No history of taking medications Lack of leg problems and problems such as leg deformity No use of herbal or chemical drugs during research to improve sleep Aged 18 years and over Non entry criteria for research Unwillingness to continue to participate during the trial Having any complications and illness in the patient's legs during the study Early discharge of the patient

Intervention groups

In the intervention group, subjects received foot massage for every 10 minutes for each leg for two consecutive days every two weeks. The control group did

not receive any intervention and received only the usual care from the center

Main outcome variables

sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170730035394N2**

Registration date: **2018-04-25, 1397/02/05**

Registration timing: **retrospective**

Last update: **2018-04-25, 1397/02/05**

Update count: **0**

Registration date

2018-04-25, 1397/02/05

Registrant information

Name

Behnam Abedini

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 935 928 0808

Email address

behnamabedini94@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

According to university regulations

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Reflexology on The Quality of Sleep in Cancer Patients Selected Hospital at Shahid Beheshti University of Medical Sciences

Public title

The Effect of Foot Reflexology on Sleep in Cancer Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with primary colorectal cancer Patient admitted to chemotherapy for the first time Earn score 5 and above Pittsburgh Sleepwick Inventory According to seven pittsburgh standards there is a problem with sleep quality Not having mental or psychological problems or mental problems Lack of diabetes Lack of leg problems and problems such as leg deformity No use of herbal or chemical drugs during research to improve sleep Aged 18 and over

Exclusion criteria:

Unwillingness to continue to participate during the trial Cause of any complications and illness in the patient's legs during the study Early discharge of the patient Acute infectious diseases during the study

AgeFrom **18 years** old to **99 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The sampling method for the study is simple random sampling method and is randomly assigned to the sequencing by blocking method and randomly divided into intervention and control groups. It should be noted that the method of hiding using the central randomization method (Central randomization). In this method, the random sequence is given to one A person is taken and samples are taken in the oncology department of the hospital. The researcher will communicate with the relevant department using the telephone, according to the order of entry of participants to the study and ask about the random allocation of the participant to the specific group.

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 committe of Shahid Beheshti University of Medical Sciences

Street address

SBMU School of Nursing & Midwifery, Vali Asr Ave, Niayesh Cross Road, Niayesh Complex, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.SBMU.PHNM.1396.756

Health conditions studied**1****Description of health condition studied**

colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

2**Description of health condition studied**

Rectum cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

3**Description of health condition studied**

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Quality of sleep or Earn score 5 and above Pittsburgh
Sleep quality index

Timepoint

Before intervention and immediately after intervention

Method of measurement

pittsburgh sleep quality index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: There are 4 reflexology massage courses, each course including two sessions in two consecutive days and intervals of each period of 2 weeks, which will last from 2 months to the end of the intervention.

Category

Treatment - Other

2

Description

Control group: Receive routine care from the center

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Mahnaz Ilkhani

Street address

Imam Hossein Hospital, Shahid Madani Avenue,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Mahrokh Dolatian

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behnam Abedini

Position

Master's Degree Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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