Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Age
From **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, Nezam Abad, Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
behnamabedini94@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mahrokh Dolatian
Street address
SBMU School of Nursing & Midwifery, Vali Asr Ave, Niayesh Cross Road, Niayesh Complex, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 2521
Email
behnamabedini94@sbmu.ac.ir
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
Street address
SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 25 3886 3342

Fax

Email

behnamabedini94@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Ilkhani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

Fax

Email

inazilkhani@gmail.com

Web page address

Person responsible for updating data

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

Street address

8 plaque, 10 metry ehdasi, 16 metry Qamar Bani Hashem, Sheikh Abad, Qom

City

Qom

Province

Tehran

Postal code

3717166881

Phone

+98 25 3886 3342

Fax

Email

behnamabedini94@sbmu.ac.ir

Web page address

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