

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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, there 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 measured 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 Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87336646458372

##### Email address

m.hesami@muk.ac.ir

##### 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 Medical Sciences

## Street address

Kurdistan University of Medical 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 departments

##### Full name of responsible person

Mahin Hesami

##### Street address

Kurdistan University of Medical 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 Medical 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

#### Full name of responsible person

Mahin Hesami

#### Position

Nursing expert/Coach Training

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kurdistan University of Medical Sciences

#### Full name of responsible person

Dr.Fathi

#### Position

PHD.Assistant Professor

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Kurdistan University of Medical Sciences

#### Full name of responsible person

Mahin Hesami

#### Position

Nursing expert / Coach Training

#### Other areas of specialty/work

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**Web page address****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*