

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of foot reflexology on anxiety in patients undergoing hemodialysis

Protocol summary

Summary

Objectives: this study will evaluate the effect of foot reflexology on anxiety of patients undergoing hemodialysis . Design: This study is a clinical trial. Setting and conduct: sampling in this study is Simple random sampling. In the sampling day, researcher will introduce himself to the patient and will present them objective of the study and if the patient agree to participate , they will enter the study according to the inclusion criteria and then they will fill the informed consent form. And also they will be divided into intervention and control group randomly. Major Inclusion criteria: patients in the weekly dialysis list who will be hemodialyzed at least 3 or 4 times and will tend to participate in the study, Major exclusion criteria: being reluctant to cooperate and use of foot reflexology . Intervention :in the intervention group, first, relaxation technique of foots will be used 2-3 time in 5 min. then foot reflexology will start with special point, the points include head point: 2 minutes, pituitary point: 30 seconds, diaphragm point: 10 times, the lungs point: 5 times , kidney and adrenal gland point 1 minute, chest ribs point: 5 times .the reflexology process will be done 30 min after the start of hemodialysis until the end of hemodialysis . The main outcome variables; anxiety scores will be decreased based on Spielberger questionnaire

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016051127841N1**

Registration date: **2016-09-22, 1395/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-22, 1395/07/01

Registrant information

Name

Solmaz Bashiriyan

Name of organization / entity

Sabzevar University of Medical Sciences, Sabzevar
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7010

Email address

s.barzegar@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of
Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on anxiety in patients
undergoing hemodialysis

Public title

The effect of foot reflexology on anxiety in patients
undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: Having at least 18 years old and at least 6 months of dialysis history; tend to participate the study; patients in the weekly dialysis list who will be hemodialyzed at least 3 or 4 times.; having full consciousness; able to Listen and speak well for answering questions; The absence of fever(>37.5), bleeding , thrombosis , numbness or paralysis of the legs.; lack of any lesions in feet ; no history of depression or anxiety disorders and mental illness; Lack of fractures and infection in the lower extremities ; ability to speak in Persian; Lack of drug addiction; Lack of diabetic neuropathy ; no history of using plantar reflexology
 Exclusion criteria: disinclination to cooperate and use of reflexology; Get a sedative drugs 4 hours prior to the intervention..

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

Gender
 Both

Phase
 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
 sampling will be done with Randomized double blocks method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

5 km road Tehran Sabzevar, Sabzevar University of Medical Sciences

City

Sabzevar

Postal code

9613874136

Approval date

2015-09-24, 1394/07/02

Ethics committee reference number

IR.MEDSAB.REC.1394.178

Health conditions studied

1

Description of health condition studied

hemodialysis

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes

1

Description

anxiety

Timepoint

after intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: After filling informed consent form in the intervention group, first, relaxation technique of foots will be used 2-3 time in 5 min. then foot reflexology will start with special point, the points include head point: 2 minutes, pituitary point: 30 seconds, diaphragm point: 10 times, the lungs point: 5 times , kidney and adrenal gland point 1 minute, chest ribs point: 5 times .the reflexology process will be done 30 min after the start of hemodialysis until the end of hemodialysis On each point, reflexology will be done by reflexology expert in 20 minute for both foot. Reflexology will be done with help of researcher and an assistant which both passed the reflexology training course. The process will be done with an stick tool which will press the skin 2.5 kg/cm.

Category

Treatment - Other

2

Description

Control group: Without the intervention by the research team and just doing hemodialysis

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital(bojnoord)

Full name of responsible person

Solmaz Bashiryan

Street address

Imam Ali Hospital, Next to Islamic Azad University,
Bojnoor Branch, Bojnoord

City

Bojnoord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Sabzevar University of
Medical Sciences

Full name of responsible person

Musa al-Reza Tadayyonfar

Street address

Sabzevar School of Nursing and Midwifery

City

Sabzevar

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 of Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Solmaz Bashirian

Position

Student

Other areas of specialty/work

Street address

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Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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Position

MSc student

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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