Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Bashiriyan

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

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Web page address
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

Contact

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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