

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Investigating the Effect of Foot Reflexology on Stress, Anxiety, Depression and Serum Cortisol levels in Hemodialysis Patients

Protocol summary

Study aim

Determination of the Effect of Foot Reflexology on Stress, Anxiety, Depression and Cortisol Serum Levels in Hemodialysis Patients at Hazrat Abolfazl Minab Hospital, 1397

Design

Clinical trial with community-based and pragmatic control group, with parallel group, one-blind, non-randomized

Settings and conduct

This study will be conducted at Abolfazl Minab Hospital. The sampling method was randomly divided into two intervention and control groups on paired and individual days. Then, based on entry and exit criteria, 30 individuals in each group were randomly selected. Blindness: We do not tell patients, doctors and nurses that patients are divided into control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Dialysis for at least 3 months and at least 3 times a week 2- Having written consent to participate in the study no use of other or complementary therapies 3-The absence of limb amputation or ulcer at the site of reflexology 4- Not having a history of taking relaxing medications and antidepressants :Exclusion criteria: 1- During the study, refer to kidney transplants or peritoneal dialysis 2- Hemodynamic complications in most dialysis sessions 3- Absent more than three sessions

Intervention groups

Intervention group: With the thumb on pressure points directly to the solar plexus and this is done 3 times a week for 4 weeks each session for 15 minutes per foot (6 minutes of pressure and 3 minutes rest and again 6 minutes of pressure) and rotationally and with the pressure applied to the patient's tolerance. Control group: By creating the same conditions with the intervention group, simple massage of the foot without compression of the standard reflexology massage points

is performed with the same duration as the intervention group.

Main outcome variables

Depression severity; Anxiety; Stress; Serum cortisol levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180304038936N2**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

Name

Ahmadreza Sayadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

a.sayadi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Foot Reflexology on Stress, Anxiety, Depression and Serum Cortisol levels in Hemodialysis Patients

Public title
The Effect of Foot Reflexology on Stress, Anxiety, Depression and Serum Cortisol levels in Hemodialysis Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years Dialysis for at least 3 months and at least 3 times a week, each time for 4-3 hours The absence of limb amputation or ulcer at the site of reflexology Absence of chronic and debilitating disease(Cancer, Chronic Respiratory Failure, Heart Failure, Rheumatoid Arthritis, Lupus Erythematosus) Not having a physical disability or a clear mental disorder that disables the patient in self-care The absence of coagulation disorders(due to the possibility of clot and thromboembolism) Not having a history of taking relaxing medications and antidepressants, cigarette and drug addiction The absence of neuropathy in the feet Not having a history of incident in the last 6 months Having written consent to participate in the study Non-use of other side therapies and complementary

Exclusion criteria:

Unwillingness to continue participation in study; During the study, refer to kidney transplants or peritoneal dialysis; Hemodynamic complications in most dialysis sessions; Absence more than three sessions; Death during the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients, doctors and nurses do not say which patients are in the control or intervention group.

Placebo
Used

Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Central Office of Medical Sciences,Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-05-09, 1397/02/19

Ethics committee reference number

IR.RUMS.REC.1397.049

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

Z63.7

ICD-10 code description

Anxiety (normal) about sick person in family Health problems within family Ill or disturbed family member Isolated family

2

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depression NOS Depressive disorder NOS

3

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

A disorder characterized by the essential descriptive features of a generalized anxiety disorder (F41.1), a panic disorder (F41.0), or a combination of both, but arising as a consequence of an organic disorder.

4

Description of health condition studied

Serum cortisol levels

ICD-10 code

E27.9

ICD-10 code description

Disorder of adrenal gland, unspecified

5

Description of health condition studied

Reflexology

ICD-10 code

ICD-10 code description

6

Description of health condition studied

Hemodialysis

ICD-10 code

Z63.7

ICD-10 code description

Dialysis (renal) NOS

Primary outcomes

1

Description

Depression scores on standard questionnaires for depression, anxiety and stress 21 questions

Timepoint

Session before and after intervention

Method of measurement

Standard questionnaire for depression, anxiety and stress 21 questions(DASS-21)

2

Description

Anxiety scores on standard questionnaires for depression, anxiety and stress 21 questions

Timepoint

Session before and after intervention

Method of measurement

Standard questionnaire for depression, anxiety and stress 21 questions (DASS-21)

3

Description

Stress scores on standard questionnaires for depression, anxiety and stress 21 questions

Timepoint

Session before and after intervention

Method of measurement

Standard questionnaire for depression, anxiety and stress 21 questions

4

Description

Serum cortisol levels

Timepoint

Session before and after intervention

Method of measurement

enzyme-linked immunosorbent assay test (ELISA test)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the stages of reflexive massage are described. Participants are asked to lie on the hemodialysis bed and close their eyes and put themselves in a state of tranquility. Foot reflexology massage is done an hour after starting dialysis for 30 minutes (15 minutes for each foot), first for the left leg and then for the right one. To massage the feet, warm your hands. Hold the heel with the left hand and bending and straightening it from the ankle with push the planter. Then enter direct pressure with the thumb on the solar plexus and this is done 3 times a week for 4 weeks each session for 15 minutes per foot (6 minutes of pressure and 3 minutes rest and again 6 minutes of pressure) and rotationally and with the pressure applied to the patient's tolerance.

Category

Rehabilitation

2

Description

Control group: By creating the same conditions with the intervention group, simple massage of the foot without compression of the standard reflexology massage points is performed with the same duration as the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Abolfazl hospital

Full name of responsible person

Reza Hadizadeh

Street address

Boulevard Muhammad, Hazrat Abolfazl hospital

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Hormozgan

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Web page address

http://www.abmh.hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ahmad Reza Sayadi

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Zahra Shanbepour

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

Ph.D.

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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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