Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Sep 2026

The effect of foot reflexology on sexual function and sexual quality of life in patients undergoing hemodialysis in Imam Reza Hospital in Sirjan in 2020

Protocol summary

Study aim
The effect of foot reflexology on sexual function and sexual quality of life in patients undergoing hemodialysis

Design
Clinical trial with intervention and sham groups, with parallel groups, one-way blind, randomized block method, on 60 patients. Block building using online software

Settings and conduct
The research environment will be Imam Reza (AS) Hospital in Sirjan. After obtaining informed written consent from the patient, information related to demographic characteristics, sexual function and quality of sexual life will be obtained through interviews in both intervention and sham groups. By assigning a specific number to each of the subjects, the person evaluating the consequences of the intervention is blinded because he does not know which person has been subjected to which type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range 18 to 65 years, no use of drugs for sexual problems, at least 3 months have passed since the beginning of their dialysis, at least 3 times a week and 4 hours each time hemodialysis, there is no medical prohibition to intervene Be, not suffering from debilitating diseases, being married and living with a spouse, no mental problems No entry conditions: Having any medical disorders while studying, death of spouse or divorce, non-intervention in three consecutive sessions

Intervention groups
Intervention group: Hemodialysis patients undergoing reflexology intervention. In addition to routine care, the foot reflexologist will receive dialysis for 4 weeks, 3 times a week for 30 minutes each (15 minutes per foot). In the sham or facade treatment group, non-specific foot massage will be performed without squeezing the standard points of reflexology with the same conditions and duration as the intervention group.

Main outcome variables
sexual function ؛ sexual quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200712048085N1**
Registration date: **2020-07-15, 1399/04/25**
Registration timing: **prospective**

Last update: **2020-07-15, 1399/04/25**
Update count: **0**

Registration date
2020-07-15, 1399/04/25

Registrant information

Name
Somayeh Zeidabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 4220 8049

Email address
somayeh.zeidabadi65@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on sexual function and sexual quality of life in patients undergoing hemodialysis in Imam Reza Hospital in Sirjan in 2020

Public title

The effect of foot reflexology on sexual function and sexual quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 65 years Do not use the drug for sexual problems At least 3 months have passed since the start of their dialysis Have hemodialysis at least 3 times a week for 4 hours each time Medically, there is no barrier to surgery, such as foot ulcers, impotence, and orthopedic problems Lack of debilitating and chronic diseases such as (cancer, chronic respiratory failure, heart failure, rheumatoid arthritis, lupus erythematosus) Being married and living with a spouse Lack of known psychological problems such as depression and bipolar disorder according to the patient's self-expression

Exclusion criteria:

Having any medical disorders during the study that prevent reflexology (such as diabetic foot ulcers, etc.) Death of spouse or divorce Failure to intervene in three consecutive sessions

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be used to assig samples to two groups (foot and sham reflexology). Blocking will be done using online software (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The size of the blocks will be 6. Using the lottery, each group will be assigned a label A, B, and then the samples will be assigned to each group based on a random block list.

Blinding (investigator's opinion)

Single blinded

Blinding description

By assigning a specific number to each of the subjects, the person evaluating the consequences of the intervention is blinded because he or she does not know which person has been subjected to which type of intervention

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

The beginning of Haft Bagh Alavi axis, campus of University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-07-06, 1399/04/16

Ethics committee reference number

IR.KMU.REC.1399.248

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

sexual function

Timepoint

mmediately and one month after the intervention (reflexology)

Method of measurement

Rosen et al.'s sexual function questionnaire for men and women

2

Description

sexual quality of life

Timepoint
mmediately and one month after the intervention (reflexology)
Method of measurement
Men and women sexual quality of life questionnaire(SQOL-F, SQOL-M)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine care, the intervention group will receive foot reflexology for 4 weeks, 3 times a week for 30 minutes each time (15 minutes per foot) during dialysis.
Category
Rehabilitation

2

Description
Control group: Control group: Non-specific foot massage will be performed without squeezing the standard points of reflexology with the same conditions and duration as the intervention group (for 4 weeks and 3 times a week for 30 minutes each time (15 minutes per foot)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital in Sirjan
Full name of responsible person
Somayeh Zeidabadi Nejad
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Quds Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Pardakhti Abbas
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Kerman, Tahmasbabad intersection, beginning of Ibn Sina St., Vice Chancellor for Research and Technology, Research Management
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Somayeh Zeidabadi Nejad
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The clinical report of this study will be presented in the form of an article.

When the data will become available and for how long
2 years

To whom data/document is available
researchers

Under which criteria data/document could be used
No specific conditions are defined.

From where data/document is obtainable
Thesis author

What processes are involved for a request to access data/document
Satisfaction of the main researcher

Comments