Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of two exercise methods (kegel and Swiss ball) on sexual distress and sexual function in women undergoing hemodialysis

Protocol summary

Study aim

Comparison of two exercise methods (kegel and Swiss ball) on sexual distress and sexual function in women undergoing hemodialysis

Design

In this study, 45 patients with dialysis entry conditions who referred to dialysis department of Kamkar, Shahid Beheshti and Vali Asr hospitals were randomly divided into two groups of intervention and one control group and each participant A code is assigned

Settings and conduct

This study will be conducted in the physiotherapy department of 3 hospitals. Eligible patients undergoing dialysis will be randomly assigned to a hospital under the intervention of Kegel Sports, at another Swiss ball, and no interventions will take place at the third hospital. pelvic contraction will measure with biofeedback device Before and after intervention. Also, the female sexual dysfunction index will be completed before and after the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female sex, age 18 and under 50 years of age, sexual dysfunction based on the female sexual dysfunction index, at least 6 months after the onset of hemodialysis exclusion criteria:Unwillingness to cooperation, smoking

Intervention groups

1. The first intervention group perform Kegel exercises for 3 times a day for 5 weeks. 2. The second intervention group performs Swiss-wing exercises for 15 sessions and 3 sessions per week under the supervision of a physiotherapist. 3. Control group: will not be subjected to an intervention.

Main outcome variables

The most important outcome of this study is the improvement of female sexual dysfunction in female under hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171107037294N2**
Registration date: **2018-05-23, 1397/03/02**
Registration timing: **retrospective**

Last update: **2018-05-23, 1397/03/02**
Update count: **0**

Registration date

2018-05-23, 1397/03/02

Registrant information

Name
mahsa haji mohammad hoseini

Name of organization / entity
qom university of mrdical science

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Iran (Islamic Republic of)

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mhajhoseini@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom university of medical sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of two exercise methods (kegel and Swiss ball) on sexual distress and sexual function in women undergoing hemodialysis

Public title
Comparison of two methods of exercise on women's sexual function under hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female gender Age over 18 and under 50 years of age Literacy of reading and writing Sexual dysfunction based on Gender Women's Sexual Function Index No hospitalization in the last 6 months Passed at least 6 months from the start Hemodialysis married
Exclusion criteria:
Unwillingness to continue cooperation Fatal or sickening Smoking Known Types of Neuropathy and Neoplasia or Genitourinary Abnormalities
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Accidental assignment is a simple randomization of hospitals to intervention and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, one intervention will be performed in each of the three hospitals and all participants will not be aware of how other interventions are carried out.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences.
Street address
Saheli st., Qom
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Qom
Province
Ghoum
Postal code
3715736994
Approval date
2017-10-31, 1396/08/09
Ethics committee reference number
IR.MUQ.REC.1396.98

Health conditions studied

1

Description of health condition studied
sexual dysfunction
ICD-10 code
ICD-10 code description

2

Description of health condition studied
patient under hemodialysis
ICD-10 code
I12.0
ICD-10 code description
Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease

Primary outcomes

1

Description
sexual function
Timepoint
before and after the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: they will perform Kegel exercises. For 3 times a day (morning, evening and night, and 15 to 20 times each time), for 5 weeks, the pelvic floor muscles are shaken for 10 seconds. Then put 10 seconds to rest, will do. After receiving the necessary training by the nurse and the physiotherapist and confirming the physiotherapist's correctness, the group trained daily at the hospital three times a week (before or after dialysis) and exercises in the presence of a physiotherapist. It will take 20 minutes
Category

Rehabilitation

2

Description
Intervention group2: they perform Swiss-ball exercises for 15 sessions and 3 sessions per week (before or after dialysis) and 20 minutes per session in a relaxed and appropriate environment under the supervision of a physiotherapist.
Category
Rehabilitation

3

Description
Control group:they will be selected as a control group and will not be interfered with.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Maryam Marvi
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Qom 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
Qom University of Medical Sciences
Full name of responsible person
Mahsa Haji Mohammad Hosseini
Position
instructor, Faculty Member
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Master
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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