

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 25 3771 1060

Email address

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

City

Qom

Province

Ghous

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

Street address

Shahid Beheshti Blvd., Qom

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2

Recruitment center

Name of recruitment center

Kamkar-Arabniya Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

VAleasr hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi

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No. 83, 1/1 Alley, Safashahr St., Qom

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dr.hosseinsaghafi@gmail.com

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

Latest degree

Master

Other areas of specialty/work

Nursery

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Fax

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