Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Kegel exercise with and without Kegel Master device on the sexual function and satisfaction in the middle-aged woman

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of Kegel exercise with and without Kegelmaster device on sexual function and satisfaction in the middle-aged woman.

Design

a clinical trial with using block randomization in two groups of 43 controls and intervention, with parallel groups.

Settings and conduct

In this clinical trial, 86 women referring to the menopause clinic of Imam Khomeini hospital in Ahvaz and the East's number one health center in Ahvaz, with poor pelvic floor muscle are randomly divided into 2 groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Middle-aged woman؛ Permanent marriage؛ A score of 28 or less with a Prinometer؛ negative urine culture Exclusion criteria: urogenital infection؛ any systemic disorders؛ Addicted to drugs and alcohol؛ Experience of severe emotional stress within the previous three months؛ Physical or mental diseases affected on sexual function؛ Taking medicines affected on sexual function؛ Having urinary incontinence؛ mental or physical problems of the husband.

Intervention groups

control group: participant will do kegel exercises without the device (including vaginal muscles contractions for 5-10 seconds, with 5-10 seconds rest in between), three times a day for thirty times, for a total duration of 12 weeks. Intervention group: participant will do exercise with kegel master device, three times a day for thirty times for a total duration of 12 weeks.

Main outcome variables

Pelvic floor muscles strength; Sexual function; sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171021036916N2**
Registration date: **2018-04-17, 1397/01/28**
Registration timing: **retrospective**

Last update: **2018-04-17, 1397/01/28**
Update count: **0**

Registration date

2018-04-17, 1397/01/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8331

Email address

tafakh.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-07, 1396/10/17

Expected recruitment end date

2018-04-07, 1397/01/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Kegel exercise with and without Kegel

Master device on the sexual function and satisfaction in the middle-aged woman

Public title
The effect of Kegel exercise with and without Kegel Master device on the sexual function and satisfaction in the middle-aged woman
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Middle-aged woman Permanent marriage A score of 28 or less with a Prinometer Normal urine culture
Exclusion criteria:
Urogenital infection Any systemic disorders Addicted to drugs and alcohol Experience of severe emotional stress within the previous three months Physical or mental diseases affected on sexual function Taking medicines affected on sexual function Underlying medical diseases Having urinary incontinence mental or physical problems of husband affecting on couple sexual function
Age
From **40 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study the subjects will be divided into two groups of 43, using block randomization.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Ahvaz Jundishapur University of Medical Sciences.
Street address
Ground Floor, Department of Research and Information Technology Jundishapur University of Medical Sciences, City University, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2017-08-21, 1396/05/30
Ethics committee reference number
IR.AJUMS.REC.1396.395

Health conditions studied

1

Description of health condition studied
Female genital prolapsed
ICD-10 code
N81
ICD-10 code description
Female genital prolapse

2

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

3

Description of health condition studied
Sexual satisfaction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sexual function
Timepoint
Before the intervention and after 3 months
Method of measurement
Standard questionnaire (FSFI)

2

Description
sexual satisfaction
Timepoint
Before and 3 months after interventions
Method of measurement
Larson s standard sexual satisfaction questionarie

Secondary outcomes

1

Description
pelvic floor muscles strength
Timepoint

Before and post treatment intervention

Method of measurement

perinometer

Intervention groups

1

Description

Control group: Each participant should lie down on the back while bending her knee.then they will be asked to perform Kegel exercises without the device (including vaginal muscles contractions for 5-10 seconds with 5-10 seconds rest in between), three times a day for thirty times, for a total duration of 12 weeks.

Category

Rehabilitation

2

Description

Intervention group: The keglemaster device will buy from the ronas medicine company.The participant will be trained to open the device first and place the spring on the nearest place of the hinge. Then, The participant lies on the back while bending her knee, and slowly put the device in her vagina and opens it till it is completely fit. While doing the Kegel exercises, if no pressure was felt inside the vagina muscle, The participant need to relocate the spring and move it one step forward. the vaginal contraction should take 2 seconds. Each participant will do the kegel exercises with a keglemaster device in three sets every day with thirty repetitions each for twelve weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

menopause clinic of Imam Khomeyni Hospital

Full name of responsible person

Samane Tafakh

Street address

Imam Khomeyni Hospital,Azadegan Sq., Ahvaz.

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6193673111

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Email

himam@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahwaz JundiShapur University of Medical Sciences

Full name of responsible person

Dr. Behzad Sharif Makhmal Zadeh

Street address

Ahwaz Jundishapur University of Medical Sciences, opposite the central building, Vice Chancellor for Research, Ahvaz University of Medical Sciences,

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saamanetafakh@yahoo.com

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, Ahwaz JundiShapur 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

Ahvaz University of Medical Sciences

Full name of responsible person

Samane tafakh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Midwifery Department, Nursing & Midwifery School, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Purandokht Afshari
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Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
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Latest degree
Master
Other areas of specialty/work
Midwifery
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available