

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison the effect of performing walking and kegel exercise on sexual dysfunction of lactating women

#### Protocol summary

2019-11-09, 1398/08/18

#### Study aim

Comparison the effect of walking and kegel exercise on sexual dysfunction of lactating women

#### Design

A randomized, controlled clinical trial with a parallel group design of 180 lactating women, will enroll and follow for 3 months.

#### Settings and conduct

Health Centers of Kermanshah

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: lactating women without unknown psychiatric problems or systemic illness; without stressful events in the last 6 months; Married and live with a permanent partner; Being in the 40 days to 6 months of postpartum period; have exclusive breastfeeding; total score  $\leq 28$  from the Rosen Sexual function Questionnaire; have ability to contract pelvic floor muscles and Singleton delivery. Exclusion criteria: Drug dependence, Marital discord, Unwillingness to participate in the study

#### Intervention groups

Intervention 1: Walking exercise Intervention 2: Kegel Exercise control group

#### Main outcome variables

Sexual function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170305032900N4**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Sousan Heydarpour

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3823 2679

##### Email address

sheydarpour@kums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2019-07-21, 1398/04/30

#### Expected recruitment end date

2019-11-21, 1398/08/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effect of performing walking and kegel exercise on sexual dysfunction of lactating women

#### Public title

The effect of exercise on sexual dysfunction of lactating women

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

lactating women without unknown psychiatric problems or systemic illness which have an effect on sexual

function; Stressful events have not occurred to them in the last 6 months; Married and live with a permanent partner; use a safe contraceptive method, during lactation (40 days to 6 months postpartum); have exclusive breastfeeding; total score  $\leq 28$  from the Rosen Sexual function Questionnaire; have ability to contract pelvic floor muscles and Singleton delivery.

**Exclusion criteria:**

Drug dependence , Marital discord, Unwillingness to participate in the study

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At first samples are selected by convenience sampling method then they will be randomly divided into three groups (two intervention and one control group). Then 180 cards that look exactly alike are numbered from one to 180 and pour into a box. Participants will be asked to bring out a card. The first 60 people are assigned to walking group, the next 60 people and the final 60 people are assigned to kegle and control group respectively.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Other

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of kermanshah University of Medical Sciences

**Street address**

Shahid Beheshti Boulevard; Central Building of Kermanshah University of Medical Sciences

**City**

kermanshsh

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2018-12-25, 1397/10/04

**Ethics committee reference number**

IR.KUMS.REC.1397.784

**Health conditions studied**

**1**

**Description of health condition studied**

sexual dysfunction

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

score of sexual function in Rosen Female Sexual Function Index

**Timepoint**

Before intervention and 3 months after intervention

**Method of measurement**

Completion of Rosen Women's Sexual Function Index

**Secondary outcomes**

**1**

**Description**

خالی

**Timepoint**

خالی

**Method of measurement**

خالی

**Intervention groups**

**1**

**Description**

Intervention group1: Group members will be instructed to walk 30 to 60 minutes three times a week and submit to the relevant checklist.

**Category**

Rehabilitation

**2**

**Description**

Intervention group 2: People will be trained to do kegel (Pelvic floor muscle contraction) exercises twice a day and submit to the relevant checklist.

**Category**

Rehabilitation

**3**

**Description**

Control group: They do not receive any intervention

**Category**

Other

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Kermanshah Health Centers

**Full name of responsible person**

parisa shadab

**Street address**School of Nursing and Midwifery, Isar Square,  
Kermanshah, Iran**City**

kermanshah

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fac\_n.m@kums.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**Vice Chancellor for Research and Technology, Shahid  
Beheshti Boulevard, Kermanshah, Iran**City**

kermanshah

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farid\_n32@yahoo.com

**Grant name****Grant code / Reference number**

دانشگاه علوم پزشکی کرمانشاه

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Sousan Heydarpour

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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sheydarpour@kums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is 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**

All participants data can be shared after being  
unidentified

**When the data will become available and for how long**

Start the access period after publishing the results

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

For use in studies allowed

**From where data/document is obtainable**

sousan Heydarpour Email: sheydarpour@kums.ac.ir  
mobile: 00989183366206

**What processes are involved for a request to access data/document**

The application will be sent to the project implementer  
by email and within 24 hours will receive the necessary  
items

**Comments**