

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Investigating the effect of counseling based on problem-solving therapy on sexual function of women undergoing complete abdominal hysterectomy by virtual group method

#### Protocol summary

##### Study aim

Determining the effect of problem-solving counseling on sexual function in women who have undergone complete abdominal hysterectomy

##### Design

A parallel clinical trial with control group, block randomized without blinding by referring to the online site of random allocation on 60 patients

##### Settings and conduct

Location: Yazd Social Security Hospital. The female sexual function questionnaire is filled in at the beginning, eight and twelve weeks after the start of the study by the intervention and control group. Classes will be done virtually by installing one of the authorized messaging software. People ask their questions in the form of online chat and receive the necessary advice. It is possible to chat privately and send SMS after class.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Smartphone access; Maximum 55 years; Complete abdominal hysterectomy due to benign disease; Three months to a year after the hysterectomy; Living in the same house with your spouse and not intending to divorce; The only wife of her husband. No entry conditions: Participate in simultaneous psychological and psychiatric interventions; Consumption of psychiatric drugs according to the patient; Addiction of yourself or your spouse according to the patient; Use of hormone replacement therapy

##### Intervention groups

The intervention group undergoes virtual sexual function training with a problem-solving approach in eight ninety-minute sessions. The control group receives male and female genital anatomy training and sexual response cycle as a pamphlet. , and after the intervention, they are consulted if they wish.

##### Main outcome variables

Women's sexual function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220601055048N1**

Registration date: **2022-06-12, 1401/03/22**

Registration timing: **prospective**

Last update: **2022-06-12, 1401/03/22**

Update count: **0**

##### Registration date

2022-06-12, 1401/03/22

##### Registrant information

##### Name

Faeghe Dehghan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 8104

##### Email address

f.dehghan@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-06, 1401/04/15

##### Expected recruitment end date

2022-12-22, 1401/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating the effect of counseling based on problem-solving therapy on sexual function of women undergoing complete abdominal hysterectomy by virtual group method

## Public title

The effect of virtual group counseling with problem solving approach on sexual function of women who have had hysterectomy

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Literacy for reading and writing Smartphone and Internet access Maximum 55 years Complete abdominal hysterectomy Hysterectomy due to benign disease Three months to a year after the hysterectomy Live in the same house with their spouse during the research period and do not intend to divorce The only wife of her husband

### Exclusion criteria:

Participate in simultaneous psychological and psychiatric interventions Taking psychiatric medication to the person's own expression Addiction of the person or spouse to the person's own expression Use of hormone replacement therapy

## Age

From **18 years** old to **55 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization by visiting the random allocation online site: The sample size consists of 60 women, who are assigned a number for each woman by visiting the online site of random allocation. Then each sample is randomly assigned to one of the two treatment groups A and B through the blocks available at <http://randomization.com>. This means that the allocation of samples to each of the two groups does not occur in A and B, respectively, but in the order in which the software output is placed.

## 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

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

##### Street address

Central Organization of Shahid Sadoughi University of Medical Sciences and Health Services, Shahid Dr. Bahonar Sq., Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

۸۹۱۶۹۷۸۴۷۷

##### Approval date

2022-03-14, 1400/12/23

##### Ethics committee reference number

IR.SSU.REC.1400.254

## Health conditions studied

### 1

#### Description of health condition studied

Sexual function of women undergoing complete abdominal hysterectomy due to benign disease

#### ICD-10 code

N99.3

#### ICD-10 code description

Prolapse of vaginal vault after hysterectomy

## Primary outcomes

### 1

#### Description

Women's sexual function score, which is measured by the Mohammadi Women's Sexual Function Questionnaire.

#### Timepoint

Calculation of female sexual function score at the beginning of the study (before the intervention), eight and twelve weeks after the start of the study

#### Method of measurement

Using Mohammadi et al.'s questionnaire, women's sexual function is measured in six areas. A higher score indicates better sexual performance.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group receives

counseling based on the problem-solving treatment on sexual function online or offline through the mobile social application channel. Meetings are once a week for 90 minutes and a total of 8 sessions.

**Category**

Treatment - Other

**2****Description**

Control group: The control group receives the anatomy training of the male and female reproductive system and the sexual response cycle in the form of a pamphlet, and after the intervention, it is consulted if desired.

**Category**

Treatment - Other

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

Shohadaye kargar (Social Security) hospital, Yazd

**Full name of responsible person**

Ali Paydar

**Street address**

Namaz Sq., Modares Blvd., Yazd

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**Fax****Email**

shohadakargar.hos@tamin.ir

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

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

International Branch of Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, km 5 of Bafgh Old Road, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8944158318

**Phone**

+98 35 3836 7634

**Email**

international@ssu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Mahshid Bakaie

**Position**

PhD in Reproductive Health, Faculty Member and Director of Midwifery Counseling Group

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of Midwifery Nursing, Bouali Alley, Timsar Fallahi St., Safaieh, Yazd

**City**

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**Province**

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**Postal code**

8916878397

**Phone**

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mah\_bokaie@yahoo.com

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

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Mahshid Bokaie

**Position**

PhD in Reproductive Health, Faculty Member and Director of Midwifery Counseling Group

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

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mah\_bokaie@yahoo.com

**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