

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

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Namaz Sq., Modares Blvd., Yazd

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

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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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

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

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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

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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