

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of psycho-sexual counseling based on the Schover model on the Sexual self-concept and sexual distress of hysterectomy women

Protocol summary

Study aim

Determining the effect of psychological-sexual counseling on sexual self-concept and sexual distress of hysterectomized women

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 100 patients. Hundreds of envelopes are placed inside the box for random allocation.

Settings and conduct

Using the random allocation method, two test and control groups are divided. One hundred envelopes are placed in the box, 50 of them will enter the intervention group if they choose the envelope containing the number 1, and 50 will enter the control group if the envelope contains the number 2. Counseling will be given to the intervention group during 4 weekly sessions at Kausar Medical Training Center, and the concerns and questions of the participants will be answered in these sessions. At the end, the control group is given a booklet of necessary training that was given to the intervention group.

Participants/Inclusion and exclusion criteria

Hysterectomy due to benign indications, Not menopausal, married, Absence of vaginismus, No addiction, satisfaction, Reluctance to continue,

Intervention groups

The intervention group will be given weekly sexual counseling during 4 sessions, in these sessions the challenges, concerns and questions of the participants will be answered. At the end, the control group is given a booklet of necessary training that was given to the intervention group.

Main outcome variables

Sexual self-concept and sexual distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230507058109N1**

Registration date: **2023-07-15, 1402/04/24**

Registration timing: **retrospective**

Last update: **2023-07-15, 1402/04/24**

Update count: **0**

Registration date

2023-07-15, 1402/04/24

Registrant information

Name

Zeinab Maloom

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3552 1720

Email address

zeinab.maloom75@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-19, 1402/02/29

Expected recruitment end date

2023-05-26, 1402/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of psycho-sexual counseling based on the Schover model on the Sexual self-concept and sexual distress of hysterectomy women

Public title

Investigating the effect of psycho-sexual counseling based on the Schover model on the Sexual self-concept and sexual distress of hysterectomy women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Be of reproductive age (18-49 years old) 6-3 months have passed since hysterectomy Subtotal and total hysterectomy without oophorectomy Have not gone through menopause before hysterectomy Be married and living His partnership with his wife should continue (not about to divorce) Not having chronic diseases such as mental disorders, physical disabilities, AIDS and hepatitis according to the patients themselves Hysterectomy due to benign indications Having at least one child Do not have vaginitis Do not have a history of vaginismus No addiction to psychoactive drugs or narcotics in couples

Exclusion criteria:

1- Absence of consent Participant does not want to continue the study Absence of even one of the counseling sessions Participant attends educational or sexual counseling sessions outside the study environment

Age

From **18 years** old to **49 months** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random allocation method (envelope), the final participants are divided into two test groups (50 people) and control (50 people). For random allocation, 100 envelopes are placed inside the box, 50 of these envelopes contain the number 1 and the other 50 contain the number 2. The participants choose one of the envelopes in the pack, if they choose the envelope containing the number 1. Enter the intervention group and if the envelope contains the number 2, enter the control group.

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 Urmia University of Medical Sciences

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Zakir St

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Province

West Azarbaijan

Postal code

6257757168

Approval date

2023-05-19, 1402/02/29

Ethics committee reference number

IR.UMSU.REC.1402.025

Health conditions studied**1****Description of health condition studied**

Hysterectomy women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sexual self-concept

Timepoint

Before and one month after the intervention

Method of measurement

Sexual self-concept questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: hysterectomized women, psycho-sexual counseling based on the Skover model during 4 weekly sessions of 90-120 minutes, the content of these sessions will include: evaluation of activity, performance and sexual relations, evaluation of concomitant diseases, mental , disabilities and examining the skills to deal with these challenges and treatments received.. Also, hysterectomy description and psychological and sexual

consequences, examination of common sexual problems after hysterectomy (decrease in the frequency of sexual activity, decrease in vaginal moisture, decrease in sexual satisfaction, decrease Sexual desire and stimulation, inability to reach orgasm, pain during intercourse, change in sensation (numbness, pain or itching), change in reaching orgasm after hysterectomy, change in body function or mental image of the body following removal of the uterus, complications side related to disease or treatment), assessment of common psychological factors after hysterectomy (distorted body image, anxiety, depression, anger, impaired sense of femininity following loss of uterus and fertility, fear of injury and loss Other organs or exacerbation of the current situation, lack of coping skills, history of sexual, emotional or psychological abuse in the past, wrong cultural-social beliefs and superstitions of pre-existing sexual patterns), familiarity with sexual function and internal and external male organs and Woman, getting to know the pattern of sexual response, describing the physiological changes of men and women during sexual activity, definitions of sexual desire, arousal, slippage, climactic climax, answering possible questions of clients, evaluating communication factors after hysterectomy (change in personal or professional roles E. Difficulties in communication, decrease in the quality of communication with a life partner, difficulty in maintaining intimacy, lack of a life partner, social determinants in relation to self-care (recommendation from others), lack of suitable conditions for establishing a private environment based on life conditions. - Clarifying and clarifying expectations, correcting misconceptions and superstitions about sex, techniques for writing down needs and expectations from sex, solutions to deal with psychological-sexual changes after surgery - providing necessary information and training about sensory focus techniques, Advice on stretching exercises and pelvic floor exercises to improve sexual function, suitable positions to reduce pain during intercourse, ways to reduce vaginal irritation and irritation, available treatments to reduce vaginal dryness and urinary incontinence, nutritional recommendations, sleep hygiene education and performing stretching and sports exercises and recommending daily walks, sleep and bedroom hygiene, explaining the components of Sternberg's love triangle - explaining the role of commitment, love and intimacy in an effective relationship with a spouse, familiarizing and emphasizing the importance of flirting and behaviors after marriage Intercourse, helping to maintain the verbal and emotional relationship with the spouse and emphasizing the importance of flirting and making love, examining the determining factors in the quality of relationships, teaching creation skills and maintaining intimacy (counseling to improve the way of talking, listening empathetically and sharing feelings in creating intimacy), finding the roots of situational/pervasive sexual desire reduction and providing a solution.. It should be noted that the content of counseling and providing information during group counseling will be advanced based on the needs and demands of the group members.

Category

Lifestyle

2

Description

Control group: Hysterectomy women, these people are not given any counseling, but after the end of the intervention, an educational package is provided to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar educational and therapeutic center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Saber Gholi Zade

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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

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Zeinab Maloum

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

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Position

Master

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Zeinab Maloum

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Student

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data is shared

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

researchers

Under which criteria data/document could be used

For research work

From where data/document is obtainable

Email

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

Email me

Comments