

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counseling based on EX-PLISSIT model on sexual function after hysterectomy

Protocol summary

Summary

This study is a Randomized controlled trial. Convenience Sampling will be done by reviewing medical records of patient in the hospital of Sari city. Based on the address and telephone recorded in the patient's files, women undergoing hysterectomy who are up to 50 years old and meet Inclusion criteria will be identified and contacted. In present meeting after gaining verbal consent, the research project will be explained, lake of anxiety and depression and existence of sexual dysfunction using DASS-21 and FSFI will be assessed, and written informed consent will be obtained. Eighty four participants will be assigned to intervention (n = 42) and control (n = 42) groups by blocked randomization. Basic tools including socio-demographic checklist, Enrich marital satisfaction questionnaire, Sexual Quality Of Life Questionnaire (SQOL-F), and Female Sexual Function Inventory (FSFI) for all participants will be completed. Sampling will be continued until to reach total sample size of the study. In the intervention group counseling based on EX-PLISSIT model will be held, at least in two one-hour counseling sessions once weekly. The number of sessions will be based on participants' needs; and at least will be two sessions. The first three levels of model (Permission, Limited Information, and Specific Suggestions) will be done; and if there are professional problems (level 4 or Intensive Therapy), the patient will be referred to specialized centers. No intervention will be done in the control group. Eight weeks after the last session, participants in both groups will complete sexual performance, marital satisfaction and sexual quality of life using the relevant questionnaires, again. If the participants wish, counseling sessions will be held in the control group after reviewing the results at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428352N3**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-15, 1395/11/27

Registrant information

Name

Roghieh Kharaghani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8144

Email address

r.kharaghani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on EX-PLISSIT model on sexual function after hysterectomy

Public title

The effect of counseling based on EX-PLISSIT model on sexual function after hysterectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria; Having a husband and lack of separation from husband; Having a maximum of 50 years; Having junior school education and more (able to complete the questionnaire); Passing at least 3 months from the hysterectomy of person; Lack of any severe psychological stress such as an accident or loss of members of first grade during the last three months; Lack of physical and mental diseases known to affect sexual activity, Such as depression, anxiety, and stress (in order of score less than 10, 8 and 15 on scales of DASS-21 questionnaire), Cut of limb or quadriplegia, phobias, vaginismus, which need treatment); Lack of using drugs and medications that affect on sexual function (anti HTN drugs, thiazide diuretics, antidepressants, antihistamines, barbiturates, narcotics, diazepam, amphetamines, drugs and alcohol); Lack of underlying medical conditions (Heart, digestive, respiratory, epilepsy, hypertension), according to own report; Sexual dysfunction (scores 28 and less in FSFI scale); Lack of surgery except hysterectomy during the past 6 months in woman and her spouse; Lack of hysterectomy because of cancer; Lack of emotional problems with husband; Absence of sexual problems or debilitating diseases of husband. Exclusion criteria; Lack of Participation in counseling sessions for any reason; Not being sexually active during follow-up period; existence of Specialized sexual problems inpatient.

Age

To 50 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Zanjan University of Medical Sciences

Street address

North Side Azadi Boulevard

City

Zanjan

Postal code

45156-13191

Approval date

2016-11-01, 1395/08/11

Ethics committee reference number

ZUMS.REC.1395.176

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

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes**1****Description**

sexual function

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

FSFI questionnaires

Secondary outcomes**1****Description**

The quality of sexual life

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

SQOL-F Questionnaire

2**Description**

sexual satisfaction

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enrich Marital Satisfaction Questionnaire

Intervention groups

1

Description

In the intervention group, 42 people, consisting of, advice is done according to EX PLISSIT model during at least two one-hour meetings on a weekly basis. intervention is done until The third step of this model, that is, ss, and in case of existence speacialized problem, the level 4 (Intensive Therapy) patients will be referred to specialized centers. The number of sessions will be based on participants' needs, at least two sessions.

Category

Behavior

2

Description

Control group of 42 people and will be performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Maryeh Mahmoodi Dangesaraki

Street address

Imam Khomeini Hospital, Amirmazndrani
Street, Sari, Mazandarn

City

Sari

2

Recruitment center

Name of recruitment center

Hekmat Hospital

Full name of responsible person

Maryeh Mahmoodi Dangesaraki

Street address

Hekmat Hospital, Taleghani Boulevard, Sari, Mazandarn

City

Sari

3

Recruitment center

Name of recruitment center

Nime Shaban Hospital

Full name of responsible person

Maryeh Mahmoodi Dangesaraki

Street address

Nime Shaban Hospital, Pasdaran
Boulevard, Sari, Mazandarn

City

Sari

4

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Maryeh Mahmoodi Dangesaraki

Street address

Shafa Hospital, Vali'e Asr Boulevard, Sari, Mazandarn

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5

Recruitment center

Name of recruitment center

Amir Mazandarani Hospital

Full name of responsible person

Maryeh Mahmoodi Dangesaraki

Street address

Amir Mazandarani Hospital, Amirmazandrani
Street, Sar, Mazandarn

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor for Research and Technology of Zanjan
University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

North Side Azadi Boulevard, Zanjan

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chancellor for Research and Technology of Zanjan
University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Chancellor for Research and Technology of

Mazandaran University of Medical Sciences
Full name of responsible person
 Dr Ahmad Ali Enayati
Street address
 Moalem Square, Sari, Mazandaran
City
 Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Chancellor for Research and Technology of Mazandaran University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty