Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, diazepins, amphetamines, drugs and alcohol); Lack of underlying medical conditions (Heart, digestive, respiratory, epilepsy, hypertension), according to owns report; Sexual dysfunction (scores 28 and less in FSFI scale); Lake of surgery exept hysterectomy during the past 6 months in woman and her spouse; Lake of hysterectomy because of cancer; Lack of emotional problems with husband; Absence of sexual problems or debilitating diseases of husband. Exclusion criteria; Lake of Participation in counseling sessions for any reason; Not being sexually active during follow-up period; existance 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
City
Sari

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

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Maryeh Mahmoodi dangesaraki

Position

Msc student of midwifery counseliing

Other areas of specialty/work

Street address

Mahmoodi Apartment, Chamran1, Alley martyr Beheshti, moalem Street, Sari, Mazandaran

City

Sari

Postal code

Phone

+98 11 3326 5513

Fax

Email

mariamahmoodi90@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Other areas of specialty/work

Street address

School of Nursing and Midwifery Zanjan, zanjan

City

Zanjan

Postal code

Phone

+98 24 3315 6344

Fax

Email

r.kharaghani@zums.ac.ir

Web page address

www.zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health/Supervisor

Other areas of specialty/work

Street address

School of Nursing and Midwifery Zanjan, Zanjan

City

Zanjan

Postal code

Phone

+98 24 3315 6344

Fax

Email

r.kharaghani@zums.ac.ir

Web page address

www.zums.ac.ir

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