

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Psycho-Sexual Counseling Based on EX-PLISSIT Model on Sexual Function and Sexual Quality of life in patients with the Most Common gynecological Cancers

Protocol summary

Study aim

Determine the Effect of Psycho-Sexual Counseling Based on EX-PLISSIT Model on Sexual Function and Sexual Quality of life in patients with the Most Common gynecological Cancers

Design

This research is a randomized clinical trial with two groups; intervention and control. Sampling will be conducted through random allocation using blocks of four

Settings and conduct

the research setting is oncology and Geneology clinic of Emem khomeini hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having reading and writing literacy, ,Having a live husband, definitive diagnosis of one of the three endometrial, cervical or ovary cancers, Stay at a time of at least 3 and not more than 6 months after the end of the surgical treatment, sexually active over the last 6 month! exclusive criteria: positive history of well-known psychiatric illness that has an effect on sexual relationships, Use of sexual desire decreasing drugs, substance abuse and alcohol consumption, Experience of bad event within 3 months before the start of the study, such as (death of loved ones and ...), Having well-known sexual dysfunction before having a cancer, positive history of attending sex education or receiving sex counseling services, Patients with cancer who are under radiotherapy, positive history of marital affair, Unwillingness to participate in any of the stages of the research and not attending more than

Intervention groups

Intervention group: Four sessions of intervention each session receives 60 to 90 minutes of psycho-sexual counseling based on the EX-PLISSIT model. Control group: The control group will not receive any intervention until the end of the research. Then, based

on the ethics of the research and their willingness Can use researcher psycho-sexual counseling.

Main outcome variables

Sexual function! Quality of sexual life

General information

Reason for update

Dear referee Due to the completion of this trial, I would be grateful if you could permit us to update the actual recruitment date. Best Regards

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029255N6**

Registration date: **2019-06-29, 1398/04/08**

Registration timing: **prospective**

Last update: **2021-10-22, 1400/07/30**

Update count: **1**

Registration date

2019-06-29, 1398/04/08

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4214

Email address

r_masoumi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01
Expected recruitment end date
 2019-08-22, 1398/05/31
Actual recruitment start date
 2019-07-01, 1398/04/10
Actual recruitment end date
 2019-12-21, 1398/09/30
Trial completion date
 2020-02-19, 1398/11/30

Scientific title
 The Effect of Psycho-Sexual Counseling Based on EX-PLISSIT Model on Sexual Function and Sexual Quality of life in patients with the Most Common gynecological Cancers

Public title
 The Effect of Psycho-Sexual Counseling Based on EX-PLISSIT Model on Sexual Function and Sexual Quality of life in patients with the Most Common gynecological Cancers

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 having reading and writing literacy Married Having a live husband A definitive diagnosis of one of the three endometrial, cervical or ovarian cancers based on medical documentation Stay at a time of at least 3 and not more than 6 months after the end of the surgical treatment Stay in remission and follow-up treatment based on medical documentation sexually active
Exclusion criteria:
 Positive history of well-known psychiatric illness that has an effect on sexual relationships (self-report) Use of sexual desire decreasing drugs(self-report) Substance abuse and alcohol consumption (self-report) Experience of bad event within 3 months before the start of the study, such as (death of loved ones and ...) Having well-known sexual dysfunction before having a cancer (self-report) Positive history of attending sex education or receiving sex counseling services Patients with cancer who are under radiotherapy Positive history of marital affair (self-report) Unwillingness to participate in any of the stages of the research and not attending more than one of the intervention sessions

Age
 From **18 years** old to **60 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **110**
 Actual sample size reached: **110**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this study, eligible participants will be assigned to two intervention and control groups through random

allocation using blocks of four.
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 Tehran University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, South Nosrat Ave., Towhid Sq.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3878

Health conditions studied

1

Description of health condition studied

Sexual function

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Quality of sexual life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

2

Description

Quality of sexual life

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The sexual quality of life-female questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Four psycho-sexual counseling sessions by group training will be received. The duration of each session will be 60 to 90 minutes.

Category

Other

2

Description

Control group: The control group will not receive any intervention until the end of the research. Then, based on the ethics of the research and their willingness the educational program will be presented by the researcher.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Raziyeh Masoumi

Street address

Tehran, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraian, the Vice Chancellor of Research at Tehran University of Medicine Sciences

Street address

Keshavarz Blv., Qods St.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Maasoumi

Position

Assistant Proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Masoumi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data of the study would be available after
unrecognizable process of participants.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Research results would be available for academic
researchers

Under which criteria data/document could be used

Research results would be available for same researches

From where data/document is obtainable

Dr. Raziyeh Masoumi email: r_masoumi@sina.tums.ac.ir

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

Sending a request by email attendance to the office of
corresponding of project presentation the reasons for
similarity of two projects studying the proposal by
corresponding of project final decision making with
corresponding author access of data in office of
corresponding author

Comments