

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Effectiveness comparison of online emotion regulation therapy (ERT) and online guided imagery therapy (GIT) on sexual anxiety in women with endometrial and ovarian cancer

#### Protocol summary

##### Study aim

Effectiveness comparison of online emotion regulation Therapy and online guided imagery therapy on sexual anxiety in women with endometrial and ovarian cancer

##### Design

Semi-experimental study conducts in parallel randomized clinical trial without blinding on 64 eligible women who have sexual anxiety. They are selected convenient sampling and randomly allocated using random allocation sequence numbers via software into 32 -women in intervention groups of ERT or GIT. They will be given the number1 to 64. Concealment is performed via closed envelope.

##### Settings and conduct

Baghaeipour Clinic of Shahid Sadoughi Hospital in Yazd, sampling, random allocation and psychological intervention will conduct by the second investigator, under the supervision of the first, third and the fourth investigators.

##### Participants/Inclusion and exclusion criteria

Inclusion age18-65 years, Having endometrial and ovarian cancer; Women able to have sex at least 6 weeks after surgery or chemotherapy; Ability to participate in counseling sessions and online consultation; Having an Android or IOS smartphone; Having sexual anxiety based on the questionnaire; Married and having intercourse with her husband; Women consent to participate in research; Ability to understand and speak Persian; Collaboration in performing tasks; exclusion Recurrence of cancer; Hospitalization; Women undergoing vaginal brachytherapy, chemotherapy, radiation; Women with cancer without hysterectomy; Women with sever surgery complications, fistula or urine/stool incontinency; Women with severe mental illness; Neurological disorders; Addiction.

##### Intervention groups

For group1(ERT) and group2 (GIT),8 counseling sessions are held weekly for 60 minutes. Both groups receive group counseling in the form of online Skyperoom and WhatsApp counseling sessions.

##### Main outcome variables

Change in the mean sexual anxiety scores

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220526054996N1**

Registration date: **2022-06-11, 1401/03/21**

Registration timing: **prospective**

Last update: **2022-06-11, 1401/03/21**

Update count: **0**

##### Registration date

2022-06-11, 1401/03/21

##### Registrant information

##### Name

Farinaz Ansari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3332 5015

##### Email address

f.ansari@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-06, 1401/04/15

##### Expected recruitment end date

2022-09-06, 1401/06/15

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Effectiveness comparison of online emotion regulation therapy (ERT) and online guided imagery therapy (GIT) on sexual anxiety in women with endometrial and ovarian cancer

**Public title**  
Comparison of online emotion regulation therapy(ERT) and online guided imagery therapy (GIT) on sexual anxiety in women with endometrial and ovarian cancer

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Age (18 to 65 years) Having Endometrial and Ovarian cancer Women able to have sex after at least 6 weeks of surgery or final chemotherapy Ability to participate in counseling sessions Having an Android or iOS smartphone Ability to use online consultation with a smart phone Having Sexual Anxiety based on the Davis Sex Anxiety Questionnaire Married women and having intercourse with her spouse Women consent to participate in the research Ability to understand and speak Persian Collaborate in performing tasks  
**Exclusion criteria:**  
 Recurrence of cancer Hospitalization of patients for any reason Women undergoing vaginal brachytherapy Women undergoing chemotherapy on time of sampling Women under radiation on time of sampling Women who have not had a hysterectomy in the presence of cancer Women with severe mental illness Neurological disorders Addiction to drugs and alcohol Women with severe surgical complications like fistula or urine/stool incontinency

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible women are selected through convenience sampling method and randomly allocated using random numbers sequence that prepared by biostatistician (using the site [www.random.org/sequences/](http://www.random.org/sequences/)) assigned into group emotion regulation Therapy (ERT) or guided imagery Therapy (GIT) (32 women in each group) by investigator based on the output of the software. Both

investigator and women are not aware the name of group that each woman will be allocated. Each woman is given a code between 1 and 64. Allocation concealment is performed using closed envelope. Again, each group is randomly allocated into two subgroups of 16 women by a colleague out of research team. Thus, the study is performed with the two main groups of emotion regulation Therapy group (n = 32 ERT) and guided imagery Therapy (n = 32 GIT), which includes four subgroups of 16 women.

#### **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

###### **Street address**

Bahonar Square,Yazd

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

8916189165

##### **Approval date**

2022-05-18, 1401/02/28

##### **Ethics committee reference number**

IR.SSU.REC.1401.014

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Sexual anxiety counseling

##### **ICD-10 code**

Z70

##### **ICD-10 code description**

Counseling related to sexual attitude, behavior and orientation

### **Primary outcomes**

#### **1**

##### **Description**

Measurement of mean sexual anxiety scores in women

with endometrial and ovarian cancer

#### **Timepoint**

At the baseline, Completion of the intervention in week 8 and follow-up completion of the study in week 12 in two groups

#### **Method of measurement**

Sexual Anxiety Questionnaire (Davis and et al.)

## **Secondary outcomes**

### **1**

#### **Description**

Mean score of wife attitude toward her spouse sexual satisfaction in two groups

#### **Timepoint**

Baseline, completion of the intervention in week 8 and follow-up of study completion in week 12

#### **Method of measurement**

With a question on a visual scale of spouse sexual satisfaction in view of wife between 1-10 by the method of self-reporting by women

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The intervention in the emotion regulation group is done online and in a group counseling method in the Skyroom and WhatsApp in 8 sessions of 60 minutes, once a week by the second investigator under the supervision of the first and the fourth couple therapist investigators. Content of sessions includes psychoeducation for sexual performance, psychoeducation for emotion and sexual emotion regulation, selection of situation and acceptance to emotional sexual response, correction of situation, extension of attention and reevaluation, self acceptance and compassion, regulation of sexual response. At the beginning of each session, a summary of the content of the previous sessions will be reviewed and the tasks assigned to the previous session will be reviewed by the counselor to assess the state of sexual anxiety improvement in each session. Women are asked to participate in online counseling discussions and ask questions. The consultant will also ask questions about the topics of the meeting to get more women involved. At the end of each session, a summary of the important issues is presented and the questions of the individuals are answered and the women are asked to do their homework until the next session.

#### **Category**

Behavior

### **2**

#### **Description**

Intervention group: The intervention in the Guided imagery group is done online and in a group in the Skyroom and WhatsApp space in 8 sessions of 60 minutes, once a week by the second investigator under

the supervision of the first and the fourth couple therapist investigators. Content of sessions includes psychoeducation for familiar with GIT, recognition of disturbance images and thoughts and their relation with sexual mood and sexual behavior, training of guided imaginary skills, thoughts rotation training and thoughts review, cognitive reconstruction of negative sexual thoughts, evaluation of sexual negative thoughts management, and assessment of sexual behaviors. At the beginning of each session, a summary of the content of the previous sessions will be reviewed and the tasks assigned to the previous session will be reviewed by the counselor to assess the state of sexual anxiety improvement in each session. Women are asked to participate in online counseling discussions and ask questions. At the end of each session, a summary of the important issues is presented and the questions of the individuals are answered and the women are asked to do their homework until the next session.

#### **Category**

Behavior

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Baghaeipour Clinic, Shahid Sadoughi Hospital, Yazd

##### **Full name of responsible person**

Tahmineh Farajkhoda

##### **Street address**

Bouali ave

##### **City**

Yazd

##### **Province**

Yazd

##### **Postal code**

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##### **Phone**

+98 35 3824 1754

##### **Email**

farajkhoda\_t@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Dr. Amir Hoshang Mehrparvar

##### **Street address**

Central Organization of Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, Dr. Bahonar Square, Yazd

##### **City**

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##### **Province**

Yazd

##### **Postal code**

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**Email**

ah.mehrparvar@gmail.com

**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**

Tahmineh Farajkhoda

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Clinical Psychologist

**Street address**

Bouali ave

**City**

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

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**Full name of responsible person**

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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**

All personal data of study participants can be shared after un identifying.

**When the data will become available and for how long**

After results publication.

**To whom data/document is available**

The data will be available to researchers working in academia and academia, and people in the industry can apply for it.

**Under which criteria data/document could be used**

Scientific usage.

**From where data/document is obtainable**

farajkhoda\_t@yahoo.com

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

One week after receiving requested email.

**Comments**