Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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/) 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 collogue 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

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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

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Bouali ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amir Hoshang Mehrparvar

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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
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

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Person responsible for updating data

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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