Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness Comparison of the Sexual Health Enhancement Program (SHE) versus the "Hold Me Tight" (HmT) Relationship Enhancement Program on Sexual Function and Marital Satisfaction in Gynecologic and Breast Cancer Survivors

Protocol summary

Study aim
To compare the effectiveness of the sexual health enhancement program with the "Hold Me Tight" relationship enhancement program on sexual function and relationship satisfaction in gynecological and breast cancer survivors

Design
Parallel randomized clinical trial with control group, random allocation with permutation block method, sample size of 33 women in each intervention group (total sample size: 66 women)

Settings and conduct
The research setting includes Baghaeipour and Ramezanzadeh clinics in Yazd. Sampling will be done by convenience method based on suitability to participate in the study among all women survivors of gynecological cancers and breast cancer in Yazd. Women will be randomly assigned to two groups. For women in both groups, 8 weekly 60-minute online counseling sessions will be held in Sky Room.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having or having a history of gynecological or breast cancers Six months after radiotherapy and chemotherapy for affected women Having sex with spouse Obtaining a score lower than 28 on the Rosen FSFI questionnaire Exclusion criteria: Cancer recurrence at the time of sampling Pregnancy Extensive surgeries in the pelvic area Women with severe surgical complications Refraining from sexual intercourse as ordered Mental disorders

Intervention groups
The first intervention group will receive the the Sexual Health Enhancement Program and the second intervention group (active control) will receive the "Hold Me Tight" program both for 8 consecutive weeks and 60-minute online counseling.

Main outcome variables
sexual function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260516069422N1**
Registration date: **2026-07-15, 1405/04/24**
Registration timing: **prospective**

Last update: **2026-07-15, 1405/04/24**
Update count: **0**

Registration date
2026-07-15, 1405/04/24

Registrant information

Name
Arefe Radaie
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-07-23, 1405/05/01
Expected recruitment end date
2026-10-23, 1405/08/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness Comparison of the Sexual Health Enhancement Program (SHE) versus the "Hold Me Tight" (HmT) Relationship Enhancement Program on Sexual Function and Marital Satisfaction in Gynecologic and Breast Cancer Survivors

Public title

Effectiveness of Sexual Health Enhancement Program versus Relationship Enhancement Program on Sexual Function and Marital Satisfaction in Gynecologic and Breast Cancer Survivors

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having or having a history of gynecological and breast cancers (recorded in the file) Six months after radiotherapy and chemotherapy for affected women Having sex with spouse Being literate Obtaining a score lower than 28 on the Rosen FSFI questionnaire Having an Android or iOS smartphone Ability and access to use the Internet and online counseling with a smartphone Willingness to participate in the study Informed consent and agreement to participate in treatment sessions

Exclusion criteria:

Cancer recurrence at the time of sampling Pregnancy Having severe marital conflicts Participating in other psychological interventions Women being hospitalized for any reason Extensive surgeries in the pelvic area Women undergoing vaginal brachytherapy Women with severe surgical complications Refraining from sexual intercourse as ordered by the relevant physician Psychological disorders (psychotic disorders and taking psychiatric medications based on medical records) Mental disorders Using alcohol, drugs, and psychotropic medications based on medical records

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of study participants to the two groups of the Sexual Health Improvement Program and the Hold Me Tight Program is done using the permutation block method. The randomization sequence is determined by a bio-statistician and is obtained by considering 15 blocks of size 4 and 1 block of size 6 after generating random numbers using software online (using the site www.random.org/sequences/). For blocks of four, each random number will be assigned one of the following permutations: ABBA, BAAB, ABAB, BABA, AABB, BBAA And for blocks of six, the random numbers will be assigned the permutation BAABBA. To ensure allocation concealment, the randomization sequence will be prepared by a bio-statistician and placed in sequentially numbered, opaque, sealed envelopes. After obtaining written informed consent from each eligible participant, the next consecutively numbered envelope will be opened by the researcher according to the participant's order of enrollment, and the participant's group assignment will be revealed. Thus, the researcher will remain unaware of the upcoming allocation until the envelope is opened, thereby preventing prediction or manipulation of the allocation sequence. Again, each group will be divided into two subgroups of 16 and 17 people using a simple random method.

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, Yazd

Street address

Yazd. Bahonar Square

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Postal code

8916189165

Approval date

2026-05-04, 1405/02/14

Ethics committee reference number

IR.SSU.REC.1405.018

Health conditions studied

1

Description of health condition studied

Endometrial Cancer

ICD-10 code

N85.02

ICD-10 code description

Endometrial intraepithelial neoplasia [EIN]

2

Description of health condition studied
ovarian cancer
ICD-10 code
E28.8
ICD-10 code description
Other ovarian dysfunction

3

Description of health condition studied
Cervical Cancer
ICD-10 code
G54.2
ICD-10 code description
Cervical root disorders, not elsewhere classified

4

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
sexual function
Timepoint
Baseline - Completion of the intervention in the 8th week - Follow-up at the end of the study in the 12th week
Method of measurement
Rosen Women's Sexual Function Index Questionnaire

Secondary outcomes

1

Description
Marital Satisfaction
Timepoint
Baseline - Completion of the intervention in the 8th week - Follow-up at the end of the study in the 12th week
Method of measurement
Hendrick Relationship Assessment Scale

Intervention groups

1

Description
Intervention Group 1: Participants in the first intervention group will receive the Hold Me Tight (HmT) Relationship Enhancement Program in eight weekly online sessions, each lasting 60 minutes, delivered via the Skyroom platform. The sessions will be conducted by the second researcher, a Master's student in Midwifery Counseling trained and certified in Emotionally Focused Therapy (EFT) under the supervision of the principal researcher (thesis supervisor), a reproductive health specialist and clinical psychologist, and the third researcher (thesis advisor), a reproductive health specialist. Each session will include didactic presentations, group discussions, question-and-answer activities, review of the previous session’s homework assignments, and assignment of homework for the following session.The Hold Me Tight (HmT) Relationship Enhancement Program consists of eight weekly sessions covering the following topics: (1) introduction to the program, attachment principles, and relationship enhancement; (2) identification of negative interaction patterns and conflict cycles; (3–4) identification of vulnerabilities and emotional injuries, and reprocessing of difficult relational interactions; (5) training in safe conversations based on the A.R.E. (Accessibility, Responsiveness, and Engagement) model, with emphasis on expressing emotional needs and feelings; (6) fostering forgiveness, acceptance, and repair of relationship injuries; (7) enhancement of emotional and sexual intimacy and management of cancer-related sexual concerns; and (8) consolidation of acquired skills, strengthening the couple’s emotional bond, and developing strategies to maintain long-term relationship improvements.
Category
Behavior

2

Description
Active Control Group: Participants in the active control group will receive the Sexual Health Enhancement (SHE) Program in eight weekly online sessions, each lasting 60 minutes, delivered via the Skyroom platform. The sessions will be conducted by the second researcher, a Master's student in Midwifery Counseling who has completed formal training in the management of sexual dysfunctions and obtained the relevant certification, under the supervision of the principal researcher (thesis supervisor), a reproductive health specialist and clinical psychologist, and the third researcher (thesis advisor), a reproductive health specialist. Each session will include educational presentations, group discussions, question-and-answer activities, review of the previous session's content and homework assignments, and assignment of homework for the subsequent session. The program is designed to enhance participants' knowledge, attitudes, and skills related to sexual health and sexual function, and to improve their sexual adjustment following cancer.The Sexual Health Enhancement (SHE) Program consists of eight weekly sessions covering the following topics: (1) introduction to the program, establishment of a safe and supportive environment, and identification of sexual concerns following cancer; (2) education on the impact of cancer and its treatments on sexual health and sexual function, correction of sexual misconceptions, and assessment of participants' sexual needs; (3–4) training in communication skills, empathy, recognition of emotional and sexual needs, and basic sexual anatomy;

(5) education on the anatomy and physiology of the sexual response, sex differences in sexual response, and the effects of cancer treatments on sexual function; (6) strategies for improving sexual function, reducing pain during sexual activity, enhancing intimacy, and gradually restoring sexual relationships; (7) addressing body image concerns and correcting misconceptions regarding sexual relationships after cancer; and (8) review of key concepts, reinforcement of acquired skills, and development of strategies to maintain long-term improvements in sexual health

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghaeipour Specialized and Subspecialty Polyclinic

Full name of responsible person

Dr. Pour Mirafazl

Street address

Yazd - Safaieh, Riazi Square, next to the main door of Shahid Sadoughi Educational and Medical Hospital

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2

Recruitment center

Name of recruitment center

Shahid Ramezanzadeh Radiotherapy Center

Full name of responsible person

Dr. Seyed Ali Akbar Mousavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amin Salehi Abargouei

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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

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Psychologist

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Person responsible for scientific inquiries

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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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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All individual data of study participants can be shared after de-identification.

When the data will become available and for how long

After publishing the results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive them.

Under which criteria data/document could be used

Scientific institutions can send their official request to the email of the scientific director of the project. After the permission of the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, the data will be sent. It is not possible to perform statistical analyses on the data.

From where data/document is obtainable

Dr. Tahmineh Farajkhoda
farajkhodatahmineh@gmail.com

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

One week after receiving the applicant's email

Comments