Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The impact of online solution-focused group counseling on the sexual quality of life and marital adjustment of women after hysterectomy

Protocol summary

Study aim
Determining the effect of Online Solution-Focused Group Counseling on Sexual Quality of Life and Marital Adjustment in Women After Hysterectomy

Design
This is a randomized, unblinded, parallel-group, controlled clinical trial conducted on 104 patients. The randomization was performed using the website https://www.sealedenvelope.com.

Settings and conduct
Sessions will be held via Google Meet over a period of 6 weeks.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Hysterectomy for benign reasons 2. Married and sexually active 3. Having just one partner 4. Within 2 months to 1 year post-surgery 5. Access to internet and communication tools 6. Not using hormone replacement therapy 7. Not receiving other educational programs 8. Not taking psychiatric medications 9. No history of mental illness 10. No medical conditions 11. No experience of traumatic or stressful events in the past six months 12. Sexual Quality of Life score less than 80 or Marital Adjustment score less than 100 Exclusion Criteria: 1. Unwillingness to continue participation 2. Absence from more than one session 3. Failure to complete assignments for more than two sessions 4. Experiencing severe stressful events during the study

Intervention groups
The intervention group will receive six online sessions of solution-focused counseling. These sessions will utilize solution-focused principles to investigate the impact of solution-focused counseling on sexual quality of life and marital adjustment in women after hysterectomy. The control group will receive their usual services and will receive the study's educational and counseling package at the end of the study.

Main outcome variables
Sexual Quality of Life After Hysterectomy Marital Adjustment After Hysterectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240601061975N1**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **prospective**

Last update: **2024-06-08, 1403/03/19**
Update count: **0**

Registration date
2024-06-08, 1403/03/19

Registrant information

Name
Mohadese Farahmandnia

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date
2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The impact of online solution-focused group counseling on the sexual quality of life and marital adjustment of women after hysterectomy

Public title

The impact of online solution-focused group counseling on the sexual quality of life and marital adjustment of women after hysterectomy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Hysterectomy for benign reasons (bleeding, mass, prolapse, pelvic pain, and adenomyosis) Being married and sexually active Having just one partner Being within 2 months to one year post-operation Having access to the internet and communication tools Not using hormonal replacement therapy (HRT) Not receiving other educational programs Not consuming psychiatric drugs No history of mental illness Absence of medical conditions (cardiac disorders, high blood pressure, respiratory diseases, thyroid disorders, epilepsy, overt diabetes) No recent experience of stressful and unpleasant events in the past six months (serious illness of self or immediate family members, death of a loved one, accidents, severe family conflicts, divorce, migration, expulsion, unemployment, bankruptcy) Quality of sexual life score less than 80 or marital adjustment score less than 100

Exclusion criteria:

Unwillingness to continue the collaboration Absence from more than one session Failure to complete assignments for more than two sessions Experiencing significant stressful events during the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to study groups using a block randomization method with block sizes of 2 and 4. This will be done using the website https://www.sealedenvelope.com/.

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

Research Ethics Committees of School of Nursing & Midwifery - Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Khwarazmi Complex, School of Nursing and Midwifery, 2nd Floor, Room C26

City

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Province

Razavi Khorasan

Postal code

9137913199

Approval date

2024-05-14, 1403/02/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1403.016

Health conditions studied

1

Description of health condition studied

Sexual Quality of Life After Hysterectomy, Marital Adjustment After Hysterectomy

ICD-10 code

(http://ap

ICD-10 code description

Z90.7Acquired absence of genital organ(s)F52.1Sexual aversion and lack of sexual enjoymentZ70.0Counselling related to sexual attitudeZ70.1Counselling related to patient's sexual behaviour and orientationZ70.8Other sex counsellingZ71.8Other specified couns

Primary outcomes

1

Description

Changes in the Average Scores of Individuals on the Simon's Sexual Quality of Life Questionnaire for Women

Timepoint

At the beginning of the study, immediately and one month after the completion of the consultation sessions.

Method of measurement

Simon's Sexual Quality of Life Questionnaire

2

Description

Changes in Average Marital Adjustment Scores of Spouses

Timepoint

At the beginning of the study, immediately and one month after the completion of the consultation sessions.

Method of measurement

Dyadic adjustment scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receive 6 online coaching sessions based on the Solution-Focused approach.

Category

Lifestyle

2

Description

Control group: It does not receive any intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Majid Hosseini

Street address

Ibn Sina Street, Imam Reza Hospital Square, Mashhad Town

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2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

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Ahmadabad Street, Ghaem Hospital, Mashhad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Fateme Hajiabadi

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Azadi Square, Eastern Gate of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Khwarazmi Educational Complex, Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Zahra Hadizade Talasaz

Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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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
The study data includes sexual quality of life scores, marital adjustment scores, demographic characteristics, and information related to hysterectomy awareness questionnaires. This data will be reported solely as numbers and average scores; the names of participants will remain confidential with the researcher.
When the data will become available and for how long
Access will begin, along with the printing of related research papers.
To whom data/document is available
The thesis will be accessible to medical researchers and students in Mashhad, and related articles will be available to all researchers.
Under which criteria data/document could be used
Individuals affiliated with scientific organizations and institutions may use this material for their research, upon request and with proper attribution and referencing of the relevant study.
From where data/document is obtainable
Contact the responsible author via email.
What processes are involved for a request to access data/document
After receiving an applicant's email, which includes their introduction and type of request, the responsible writer will review the necessary information and send it to the applicant as soon as possible.
Comments