Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Oct 2026

Effectiveness of online and face to face positive psychology counseling on sexual intimacy in women undergoing hysterectomy due to benign reasons.

Protocol summary

Study aim

Effectiveness of online and face to face positive psychology counseling on sexual intimacy in women undergoing hysterectomy due to benign reasons.

Design

The study is a randomized clinical trial with parallel groups without blinding and it is conducted on 66 eligible women with a history of vaginal hysterectomy. Simple randomization is done based on the output of the Random Allocation software.

Settings and conduct

The research environment is the Shohadaye Kargar Hospital in Yazd and the selection of samples from women eligible for random allocation and positive counseling intervention is carried out by the second researcher under the supervision of the first, third and fourth researchers. Face-to-face counseling sessions at the sampling site and virtual counseling sessions through The virtual network software is Iranian version.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 60 years. The cause of hysterectomy is benign. The type of hysterectomy should be complete abdominal. Three months to two years have passed since the hysterectomy. Have a common bed with her husband. Be the only wife of her husband Have access to a smart phone and the Internet. Non-entry criteria: Participation in psychological and psychiatric interventions at the same time. taking psychiatric drugs (according to the patient). Have done a vaginal hysterectomy.She or her husband have addiction (according to the patient)

Intervention groups

For the virtual intervention group, 8 sessions of 90 minutes with an interval of one week will be held virtually in line with education (positive approach in sexual relations). And for the face-to-face intervention group, training will be held in the form of 8 sessions of 90 minutes based on (positive-oriented approach in sexual relations) once a week at the sampling center in person.

Main outcome variables

Sexual intimacy score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230209057373N1**
Registration date: **2023-04-19, 1402/01/30**
Registration timing: **prospective**

Last update: **2023-04-19, 1402/01/30**
Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Orly Nazanin Kalimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of online and face to face positive psychology counseling on sexual intimacy in women undergoing hysterectomy due to benign reasons.

Public title

Effectiveness of online and face to face positive psychology counseling on sexual intimacy in women undergoing hysterectomy due to benign reasons.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 60 years The cause of hysterectomy is benign The type of hysterectomy should be complete abdominal Three months to two years have passed since the hysterectomy. Have a common bed with her husband Be the only wife of her husband Have access to a smart phone and the Internet.

Exclusion criteria:

Participation in psychological and psychiatric interventions at the same time taking psychiatric drugs (according to the patient). Have done a vaginal hysterectomy. She or her husband have addiction (according to the patient)

Age

From **20 years** old to **60 years** old

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

66 women with a history of hysterectomy have a record of hospitalization in Shohadaye Kargar Hospital of Yazd and are included in the study based on the entry and exit criteria.Sampling in this research will be done by simple random allocation method.So that by the expert of biostatistics using simple randomization method and sequence of random numbers with random allocation software, these women are divided into two groups of 33 people: virtual positive counseling (intervention group) and face-to-face positive counseling (control group). At the beginning of the study, people are told that they have the same chance to be in each intervention group. And except for the biostatistics researcher, no one (not the students, supervisors and advisors and not the participants) knows in which group they will be allocated.

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

Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Bld., Yazd

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.SSU.REC.1401.080

Health conditions studied

1

Description of health condition studied

Sexual intimacy counseling

ICD-10 code

Z70.8

ICD-10 code description

Other sex counselling

Primary outcomes

1

Description

Change in mean scores of sexual intimacy in women

Timepoint

Measuring the sexual intimacy score at the beginning of the study (before the start of the intervention) and 8 and 12 weeks after the start of virtual and face-to-face counseling

Method of measurement

Women's Sexual Intimacy Questionnaire (Botlani et al.)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The virtual counseling group is subjected to the protocol of counseling and question and answer during 8 counseling sessions for 90 minutes, a positive approach in sexual relations where both the content of the sessions are presented and the questions are answered. Counseling by a researcher who is studying counseling in midwifery and has obtained the certificate of ability to complete the positive-oriented approach counseling course under the supervision of supervisors, the counselor is implemented. In the intervention group, there are 8 virtual group counseling sessions of 90 minutes, the content of the positive-oriented approach sessions with The subject of the effect of a positive cognitive approach on sexual satisfaction and marital compatibility, which has been approved by supervisors, advisors, referees, and supervisors, is prepared in a multimedia format and one day a week in a virtual way by installing one of the software The authorized messengers are carried out on mobile phones of the research units and they are asked to ask their questions in the form of online chat and receive the necessary advice and guidance from the researcher.

Category

Behavior

2

Description

Control group: the face-to-face intervention or control group, the content of the sessions is the same as the virtual intervention group, with the difference that one session per week is held as a group according to the planning between the researcher and the clients by the researcher at Shohada Karegar Hospital. In the control group, there were 8 face-to-face group counseling sessions, 90 minutes, with the content of the positive approach sessions on the topic of the effect of the positive cognitive approach on sexual satisfaction and marital adjustment by a researcher who studies counseling in midwifery and a certificate of ability to complete the positive approach counseling course. It is implemented under the supervision of supervisors and advisors.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-ye Kargar Hospital, Yazd

Full name of responsible person

Mahshid Bokaie

Street address

School of Midwifery Nursing., Bouali Alley., Teymsar Fallahi St., Safaieh., Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Mahshid Bokaie
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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
Undecided - It is not yet known if there will be 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 results publication.
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 usage.
From where data/document is obtainable
mah_bokaie@yahoo.com
What processes are involved for a request to access data/document
One week after receiving the applicant's email.
Comments