Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

the effect of cognetive-behavioral group counseling on the sexual self-esteem and genital self-image in the women seeking genital cosmetic surgry

Protocol summary

Study aim

Determining the effect of cognitive-behavioral group counseling on genital self-image and sexual self-esteem of women applying for genital cosmetic surgery

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 70 people undergoing genital cosmetic surgery. For randomization, rand function of Excel software was used. Randomization unit: individual How to make a random sequence: block randomization with a block size of four (randomization of replaced blocks) How people enter the random sequence: according to the sequence created by the Random Allocation Software

Settings and conduct

Study implementation platform: Neyshabor Gynecologists' Office . The method of gathering information will be through filling out questionnaires.. The intervention will be in the form of counseling sessions, during 8 90-minute sessions twice a week in the form of presentation of PowerPoint, questions and answers, and dynamic relationship for the people in the intervention group. Attendance at a counseling center will be done. . The number of women present in the meetings will be 11-12 people (three groups).

Participants/Inclusion and exclusion criteria

Inclusion criteria:. Don't be pregnant. Age between 18 and 50 years and performing genital cosmetic surgery Having no medical indication for genital cosmetic surgery Exclusion criteria: Participation in more than two sessions of non-consultation

Intervention groups

Intervention group: women applying for genital cosmetic surgeries who will receive 8 sessions of cognitive-behavioral counseling in person. Control group: will not receive counseling.

Main outcome variables

The change of the total score of sexual self-esteem and genital self-image score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230426058001N1**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **retrospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Hamide Mollanorouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4334 2611

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of cognetive-behavioral group counseling on the sexual self-esteem and genital self-image in the women seeking genital cosmetic surgry

Public title

the effect of counseling on the sexual self-esteem and genital self-image

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be Iranian Not pregnant Not menopause There is no medical indication for genital cosmetic surgery according to the gynecologist's opinion. have written informed consent to participate in the research Be between 18 and 50 years old Apply for genital cosmetic surgery Have at least a cycle certificate and a smartphone Don't have severe stress, anxiety and depression Do not participate in cognitive behavioral counseling or training classes at the same time There should be no addiction to alcohol and drugs in the woman and her husband Unfortunate incidents have not happened to him in the last 6 months.

Exclusion criteria:

Failure to participate in more than two counseling sessions Occurrence of accidents during the study Incomplete completion of questionnaires (response rate less than 90%)

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized clinical trial with a pre-test and post-test plan will be conducted on 70 women applying for genital cosmetic surgery (before and after cosmetic surgery) referring to private offices and clinics and beauty centers in Neishabur city. After obtaining permission from the ethics committee of the university and receiving a letter of introduction from the research vice-chancellor of the Mashhad Midwifery Nursing School, the researcher will conduct sampling by visiting beauty clinics and gynecologists' offices daily. Sampling will be done among the eligible applicants for genital cosmetic surgery by the available method. Then the objectives and method of the research will be explained to them by the researcher. If they are willing and meet the entry criteria, written consent will be obtained from them to enter the research. Then they will be randomly divided into intervention and control groups. Randomization Unit: Individual How to make a random sequence: Permuted block randomization with a block size of four How people enter the random sequence: according to the sequence created by the Random Allocation Software

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 Mashhad University of Medical Sciences

Street address

University St., Ibn Sina St., Dr. Crossroad, Faculty of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-03-04, 1401/12/13

Ethics committee reference number

IR.MUMS.REC.1401.400

Health conditions studied

1

Description of health condition studied

Healthy people willing to undergo unnecessary cosmetic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changing the sexual self-esteem score.

Timepoint

Before the start of the intervention and one month after the end of the intervention (counseling sessions)

Method of measurement

Zina and Schwarz sexual self-esteem questionnaire - shortened form.(SSEI-W-SF).

2

Description
Changing the genital self-image score
Timepoint
Before the start of the intervention and one month after the end of the intervention (counseling sessions)
Method of measurement
Genital self-image questionnaire.(FGSIS)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, group cognitive-behavioral counseling is held face-to-face in 8 sessions of 90 minutes twice a week. The number of women present in the meetings will be 11-12 people (three groups). The content of the sessions includes: introduction, explanation of the work method and the type of counseling and the research goal of people's cognitive reconstruction, including the process of identifying and evaluating ineffective and unhelpful spontaneous thoughts, as well as ineffective coping behaviors. In the field of self-image and body image and sexual self-esteem, identifying and evaluating cognitive distortions, realistically looking at the individual valuation system, identifying strengths and weaknesses and correcting them. At the end of each
Category
N/A

2

Description
Control group: Women applying for genital cosmetic surgery who will not receive any advice.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecologists' office in Neishabur city and beauty clinics
Full name of responsible person
Hamide sadat Mollanorouzi
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Attar street.Attar 9
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Kobra Mirzakhani
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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
Hamide Sadat Mollanorouzi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available