

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

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

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

Email address

mollanorouzih981@mums.ac.ir

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	Individual
Trial completion date	How to make a random sequence: Permuted block randomization with a block size of four
empty	How people enter the random sequence: according to the sequence created by the Random Allocation Software
Scientific title	Blinding (investigator's opinion)
the effect of cognitive-behavioral group counseling on the sexual self-esteem and genital self-image in the women seeking genital cosmetic surgery	Not blinded
Public title	Blinding description
the effect of counseling on the sexual self-esteem and genital self-image	Placebo
Purpose	Not used
Education/Guidance	Assignment
Inclusion/Exclusion criteria	Parallel
Inclusion criteria:	Other design features
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.	Secondary Ids
Exclusion criteria:	empty
Failure to participate in more than two counseling sessions Occurrence of accidents during the study Incomplete completion of questionnaires (response rate less than 90%)	Ethics committees
Age	1
From 18 years old to 50 years old	Ethics committee
Gender	Name of ethics committee
Female	Ethics committee of Mashhad University of Medical Sciences
Phase	Street address
N/A	University St., Ibn Sina St., Dr. Crossroad, Faculty of Nursing and Midwifery
Groups that have been masked	City
No information	Mashhad
Sample size	Province
Target sample size: 70	Razavi Khorasan
Randomization (investigator's opinion)	Postal code
Randomized	9137913199
Randomization description	Approval date
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:	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).

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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

Street address

Attar street.Attar 9

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Kobra Mirzakhani

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Razavi Khorasan, University St., 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

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