

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effect of counseling based on cognitive-behavioral approach on self-esteem of hysterectomized women in reproductive ages

Protocol summary

Study aim

Determination of the effect of counseling based on cognitive-behavioral approach on self-esteem of hysterectomized women in reproductive ages

Design

This research is a clinical trial with pretest-post test design with control group and with parallel groups without blindness. The sample size is 40 people and will be divided into two groups of control and test according to the random numbers table .

Settings and conduct

This research will be carried out on women of reproductive age in the Imam Hospital of Ahvaz. To select samples from the available sampling method, they will be invited by telephone call. After obtaining the consent and justification of the participants about the goals of the study and its implementation, as well as ensuring the confidentiality of the results, the demographic questionnaire and Rosenberg self-esteem are completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria include women of reproductive age of 15-45 years, at least 2 months have passed since hysterectomy, have reading and writing skills, physical and mental health, gain less than 15 points in the Rosenberg Self-Esteem Questionnaire. Exclusion criteria include taking psychiatric drugs, history of preoperative psychiatric disorders, severe depression, history of mastectomy and history of uterine cancer.

Intervention groups

The test group will receive 12 sessions of 60 minutes, group cognitive-behavioral counseling, twice a week. The control group does not receive intervention. After the end of the study, they will receive a educational CD of meetings for observance of ethical standards.

Main outcome variables

Mean score of self-esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180222038828N1**

Registration date: **2018-05-11, 1397/02/21**

Registration timing: **prospective**

Last update: **2018-05-11, 1397/02/21**

Update count: **0**

Registration date

2018-05-11, 1397/02/21

Registrant information

Name

Golnoosh Mohamadnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-20, 1397/02/30

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of counseling based on cognitive-behavioral approach on self-esteem of hysterectomized women in reproductive ages		City Ahvaz	
		Province Khouzestan	
		Postal code 61357-15794	
Public title The effect of cognitive-behavioral approach on women's self-esteem		Approval date 2018-01-23, 1396/11/03	
Purpose Treatment		Ethics committee reference number IR.AJUMS.REC.1396.908	
Inclusion/Exclusion criteria Inclusion criteria: Women of reproductive age of 15-45 years At least 2 months have passed since hysterectomy Have reading and writing skills Have physical and mental health Having a score of less than 15 in the Rosenberg Self-Esteem Questionnaire Exclusion criteria: Taking psychiatric drugs History of psychiatric disorders Before surgery Major depression History of mastectomy History of uterine cancer		Health conditions studied 1 Description of health condition studied Hysterectomy ICD-10 code Z90.7 ICD-10 code description Acquired absence of genital organ(s)	
Age From 15 years old to 45 years old		Primary outcomes 1 Description Self-esteem Timepoint Before the intervention, one week after the intervention, one month after the intervention Method of measurement Rosenberg self-esteem questionnaire	
Gender Female		Secondary outcomes empty	
Phase N/A		Intervention groups 1 Description Intervention group: Twelve sessions of cognitive behavioral intervention . The duration of each session is 60 minutes and twice a week. Category Behavior	
Groups that have been masked <i>No information</i>		2 Description No intervention Category Other	
Sample size Target sample size: 40		Recruitment centers 1 Recruitment center Name of recruitment center	
Randomization (investigator's opinion) Randomized			
Randomization description Individuals will be randomly assigned to one of the two test and control groups using simple randomization sequences. and hiding random allocation through the use of sealed non-transparent envelopes.			
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 Ahvaz Jundishapur University of Medical Sciences Street address Assistant Professor of Research and Information Technology, Ahvaz Jundishapur University of Medical Sciences, Ground floor			

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
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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
Ahvaz 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

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Position
Master's degree in midwifery counseling
Latest degree
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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