Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effectiveness of cognitive-behavioral therapy counseling on perceived stress and fear of negative evaluation in hysterectomized women of reproductive age.

Protocol summary

Study aim

The effect of cognitive behavioral counseling on perceived stress and fear of negative evaluation in hysterectomy women at childbearing age

Design

It is a clinical trial with a pre-test-post-test design with a parallel control group and without blinding. The sample size includes 72 people and they will be divided into two control and test groups based on the table of random numbers.

Settings and conduct

This research will be conducted on hysterectomized women of reproductive age in Imam Ahvaz Hospital. In order to select the samples from the available sampling method, they are invited to cooperate through a phone call. After obtaining the consent and justification of the participants regarding the objectives of the study and the method of implementation, as well as ensuring the confidentiality of the results, the demographic questionnaire, the perceived stress questionnaire, and the fear of negative evaluation questionnaire are completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria Women 18 to 45 years old; At least 2 months and at most 12 months have; passed since hysterectomy; Being literate in reading and writing; Having a minimum score higher than 21.8 in the fear of negative evaluation questionnaire and 24 in the perceived stress questionnaire; Married women with husbands; Hysterectomy women; Having at least two children. Exclusion criteria; Diagnosis of malignancy before or after hysterectomy surgery; Taking psychiatric drugs; Women with primary infertility; History of mastectomy

Intervention groups

The test group will receive 10 group CBT sessions for 90 minutes, 2 times a week. The control group does not receive any intervention. After the end of the research, they will receive an educational CD of the sessions in order to comply with the ethical standards

Main outcome variables

Average score of perceived stress; fear of negative evaluation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240523061874N1**
Registration date: **2024-06-17, 1403/03/28**
Registration timing: **prospective**

Last update: **2024-06-17, 1403/03/28**
Update count: **0**

Registration date

2024-06-17, 1403/03/28

Registrant information

Name

seddigheh rashidimoghaddan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 378 8273

Email address

saeederashidi1989@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-05, 1403/04/15

Expected recruitment end date

2024-11-05, 1403/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the effectiveness of cognitive-behavioral therapy counseling on perceived stress and fear of negative evaluation in hysterectomized women of reproductive age.

Public title
The effect of cognitive-behavioral counseling on perceived stress and fear of negative evaluation

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Women 18 to 45 years old At least 2 months and at most 12 months have passed since hysterectomy Being literate in reading and writing Having a minimum score higher than 21.8 in the fear of negative evaluation questionnaire and 24 in the perceived stress questionnaire Married women with husbands Hysterectomy women Having at least two children

Exclusion criteria:
Diagnosis of malignancy before or after hysterectomy Use of psychiatric drugs History of mental illnesses before surgery Previous history of using cognitive behavioral methodology Women with primary infertility History of mastectomy

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning the intervention to people is randomly and by the method of randomized permutation blocks with random block sizes of 4, 6 and 8 (using the table related to random permutations). The randomization list will be prepared by the statistician. The intervention used in this research is allocated according to the randomized list by a person outside the study who is not aware of the research objectives and according to the corresponding codes in the sealed 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 Jundi Shapur Ahvaz University of Medical Sciences

Street address
Vice-Chancellor of Research and Information Technology, Jundishapur University of Medical Sciences and Health Services, Ahvaz, ground floor

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2024-06-02, 1403/03/13

Ethics committee reference number
IR.AJUMS.REC.1403.102

Health conditions studied

1

Description of health condition studied
Hysterectomy

ICD-10 code
Acquired a

ICD-10 code description
Z90.7

Primary outcomes

1

Description
Perceived stress and fear of negative evaluation

Timepoint
Before the intervention, one month after the intervention

Method of measurement
Questionnaire of perceived stress and fear of negative self-evaluation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receives ten sessions of cognitive behavioral intervention. The duration of each session is 90 minutes and twice a week
Category
Behavior

2

Description
Control group: No intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ahvaz Hospital
Full name of responsible person
Seddighe Rashidi Moghaddam
Street address
Imam Hospital, Azadegan St
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3222 2085
Fax
Email
himam@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Vice-Chancellor of Research at Jundishapur University of Medical Sciences and Health Services, Ahvaz
Street address
ground floor, Jundishapur University of Medical Sciences and Health Services Research Vice-Chancellor, Ahvaz,iran
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3333 3477
Email
saeederashidi1989@gmail.com
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
Ahvaz University of Medical Sciences
Full name of responsible person
Seddighe Rashidi Moghaddam
Position
Master's student in counseling in midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Golestan Boulevard, Golestan Hostel
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3321 4581
Email
saeederashidi1989@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mitra Tedin Najafabadi
Position
Master of Midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Jundishapur University, Faculty of Nursing and

Midwifery

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3333 3311

Email
tadayon_m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Seddighe Rashidi Moghaddam

Position
Master's student in counseling in midwifery

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Golestan Boulevard, Golestan Hostel

City
Ahvaz

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Khouzestan

Postal code
61357-15794

Phone
+98 61 3321 4581

Email
saeederashidi1989@gmail.com

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