Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of acceptance and commitment-based group counseling on the genital self-image and sexual self-esteem of newly married women

Protocol summary

Study aim
Determining the effect of group counseling based on acceptance and commitment on genital self-image and sexual self-esteem in newly married women.

Design
A randomized controlled clinical trial with parallel groups and single-blind design. Randomization will be performed using Randomization.com.

Settings and conduct
The Acceptance and Commitment Therapy (ACT) group counseling will be delivered by the researcher, a master's student in midwifery counseling. The intervention consists of 8 group sessions, each lasting 90 minutes, held twice per week with 9–10 participants per group, at the Family Health Center. This study follows a single-blind design, in which the statistical analyst will remain unaware of the group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 45, literacy in reading and writing, living together with a spouse for at least 6 months to 3 years, obtaining a score of 21 or lower on the Genital Self-Image Scale. Exclusion criteria: Taking medication due to physical or psychological problems, simultaneous participation in individual psychosexual therapy, couples therapy, or acceptance and commitment-based psychotherapy within the past 3 months or planned during the study period, substance/alcohol use, being pregnant, and having a history of childbirth.

Intervention groups
Intervention group: Receive 8 sessions of group counseling based on Acceptance and Commitment Therapy (ACT), delivered twice per week. Control group: Will not receive any intervention. Ĩ

Main outcome variables
Genital Self-Image Sexual Self-Esteem

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221217056842N5**
Registration date: **2025-09-25, 1404/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-25, 1404/07/03**
Update count: **0**

Registration date
2025-09-25, 1404/07/03

Registrant information

Name
Mansoureh Refaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0535

Email address
mansourehrefaei@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-11, 1404/06/20

Expected recruitment end date
2026-03-19, 1404/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of acceptance and commitment-based group counseling on the genital self-image and sexual self-esteem of newly married women

Public title
The Effect of acceptance and commitment-based group counseling on the genital self-image and sexual self-esteem of women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 35 History of marital life with the spouse for at least 6 months up to 3 years obtaining a score of 21 or lower on the Genital Self-Image Scale literacy in reading and writing Being in the first marriage
Exclusion criteria:
Taking medication due to physical or psychological problems simultaneous participation in individual psychosexual therapy, couples therapy or acceptance and commitment-based psychotherapy within the past 3 months or planned during the study period substance/alcohol use being pregnant having a history of pregnancy Presence of severe marital conflict according to the participant's self-report Experience of major adverse life events during the past 6 months (based on self-report)
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the participants, they will be assigned to the control and experimental groups using the random block allocation method. In this method, blocks of four are created with a 1:1 ratio, meaning that in each block of four participants, two are assigned to the control group and two to the experimental group. The sequence of random allocation will be determined online by the supervisor. Then, the intended sequence will be written on paper sheets for each participant using the codes A and B. Each sheet will then be placed in an opaque, sealed envelope. The envelopes will be sequentially numbered (for example, from 1 to 96). Upon each participant's entry into the study, the researcher will take an envelope from the box in numerical order and, based on its contents, assign the individual to the relevant group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The statistical analyst will be blinded to the study groups, and the data will be entered into the software using codes A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
65178-38698
Approval date
2025-08-30, 1404/06/08
Ethics committee reference number
IR.UMSHA.REC.1404.406

Health conditions studied

1

Description of health condition studied
Low genital self-image
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Genital self image
Timepoint
Before the intervention and one month after the completion of the intervention
Method of measurement
Female genital self image scale

2

Description
Sexual Self-Esteem
Timepoint
Before the intervention and one month after the completion of the intervention
Method of measurement
Sexual Self-Esteem Index for Woman-Short Form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving an Acceptance and Commitment Therapy (ACT) intervention consisting of 8 sessions, each lasting 60–90 minutes, conducted in groups of 9–10 participants, held twice per week.
Category
Behavior

2

Description
Control group: This group will not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Family Health Center
Full name of responsible person
Mansoureh Refaei
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Fahmide
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
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Hamadan
Postal code
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Phone
+98 81 3131 4058
Email
Fanavari@umsha.ac.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
mansoureh refaei
Position
Associate professor
Latest degree
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Other areas of specialty/work
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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