Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating The Effectiveness of Acceptance and Commitment Therapy on Sexual Function, Sexual Quality of Life, and Marital Intimacy After Childbirth in Women Attending Comprehensive Health Centers

Protocol summary

Study aim
Determining The Effectiveness of Acceptance and Commitment Therapy on Sexual Function, Sexual Quality of Life, and Marital Intimacy After Childbirth in Women Attending Comprehensive Health Centers

Design
A Randomized Controlled Clinical Trial With Parallel Groups Will Be Conducted On 50 Women With A History Of Childbirth. Randomization Will Be Performed Through A Card-Based Lottery Method

Settings and conduct
The Study Is Conducted At Comprehensive Health Service Centers Of Shahrekord. Using A Pretest-Posttest Design On 50 Women, Who Score Below The Cutoff Point On The Female Sexual Function Index. Participants Are Randomly Assigned To Intervention And Control Groups. The Intervention Group Receives Eight Sessions Of Acceptance And Commitment Therapy , While The Control Group Does Not Receive This Intervention. Data will be Collected Using Standardized Questionnaires Before and After the Intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Informed Consent, Married, 2-6 Months Postpartum, Exclusive Breastfeeding, No Interfering Illness, No Genital Surgery, No Psychological Treatments, No Addiction. Exclusion Criteria: Pregnancy, Stressful Events In The Past 6 Months, Medication Use

Intervention groups
Members Of The Intervention Group, In Addition To Routine Care, Will Participate In Eight 90-Minute Sessions (Once a week) Of Acceptance And Commitment Therapy. While The Control Group Will Receive Only Routine Care. Throughout The Study, Both Groups Will Receive Routine Services From Health Centers

Main outcome variables
Sexual Function, Sexual Quality of Life, Marital Intimacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250804066759N1**
Registration date: **2025-09-16, 1404/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-16, 1404/06/25**
Update count: **0**

Registration date
2025-09-16, 1404/06/25

Registrant information

Name
Shiva Alizadeh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 4253 0107

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-06, 1404/06/15

Expected recruitment end date
2025-12-06, 1404/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating The Effectiveness of Acceptance and Commitment Therapy on Sexual Function, Sexual Quality of Life, and Marital Intimacy After Childbirth in Women Attending Comprehensive Health Centers

Public title
Evaluating The Effectiveness of Acceptance and Commitment Therapy on Sexual Function, Sexual Quality of Life, and Marital Intimacy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having Informed Consent to Participate in the Study Being Married Being Sexually Active (At Least Within the Past 4 Weeks) Having Passed a Minimum of 2 Months and a Maximum of 6 Months Since Childbirth Continuation of Exclusive Breastfeeding No History of Diagnosed Psychological Disorders in the Past 6 Months No Chronic or Acute Physical or Psychological Illnesses (Such as Diabetes, Hypertension, Severe Genitourinary Infections, Sudden Pelvic Injuries, Fractures, Stroke) That, in the Judgment of the Research Team, May Interfere With the Implementation of the Intervention or the Assessment of Its Outcomes No History of Cosmetic Surgery in the Genital Area Not Currently Receiving Any Concurrent Psychological Interventions No Addiction to Cigarettes, Hookah, or Similar Substances

Exclusion criteria:
Pregnancy Occurrence of Any Stressful Life Event (Such as the Death of First-Degree Relatives) In The Past 6 Months Any Medication That May Significantly Affect Sexual Function or Psychological Status, Such as Antidepressants, Anticonvulsants, or Hormonal Medications

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants Who Meet The Inclusion Criteria Will Be Recruited Using A Convenience Sampling Method. Initially, All Eligible Individuals Will Complete The Female Sexual Function Index (FSFI) Questionnaire. Those Who Score Below The Cutoff Point Of 28 On The FSFI Will Be Randomly Assigned To Either The Intervention Group Or The Control Group, With 25 Participants In Each Group. For The Purpose Of Randomization, 25 Cards Labeled "A" And 25 Cards Labeled "B" Will Be Thoroughly Mixed And Placed In An Envelope. Each Participant Will Randomly Draw One Card From The Envelope. The Label On The Selected Card Will Determine The Participant’s Group Allocation (A = Intervention Group, B = Control Group)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Since The Possibility Of Participant Influence In Group Sessions Is One Of The Common Challenges In Group-Based Interventions, A Specialist Psychologist Will Be Present In All Group Training Sessions Alongside The Researcher. This Is Planned To Manage The Situation By Guiding Discussions, Controlling Interactions, And Preventing Dominance Of Individual Opinions, Thereby Reducing Potential Side Effects.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Central Administration Building, Shahrekord University of Medical Sciences and Health Services, Ayatollah Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Approval date
2025-08-02, 1404/05/11

Ethics committee reference number
IR.SKUMS.REC.1404.059

Health conditions studied

1

Description of health condition studied
Sexual Function

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Sexual Quality of Life

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Marital Intimacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual Function Score On The Rosen's Standard Female Sexual Function Index Questionnaire
Timepoint
Before The Start Of The Intervention, And Ten Days After The End Of The Intervention
Method of measurement
Rosen's Standard Female Sexual Function Index Questionnaire

2

Description
Sexual Quality Of Life Score On Symonds' Sexual Quality Of Life-Female (SQOL-F) Questionnaire
Timepoint
Before The Start Of The Intervention, And Ten Days After The End Of The Intervention
Method of measurement
Symonds' Sexual Quality Of Life-Female (SQOL-F) Questionnaire

Secondary outcomes

1

Description
Marital Intimacy Score On Thompson And Walker's Marital Intimacy Questionnaire
Timepoint
Before The Start Of The Intervention, And Ten Days After The End Of The Intervention
Method of measurement
Thompson And Walker's Marital Intimacy Questionnaire

Intervention groups

1

Description
Intervention group: Members Of The Intervention Group Will Participate In Eight Weekly 90-Minute Sessions Of Acceptance And Commitment Therapy (ACT). This Intervention Will Be Designed And Implemented Based On The Standard ACT Protocol To Teach The Core Principles Of The Approach In A Structured, Step-By-Step Manner. In Each Session, One Of The Main Components Of ACT, Tailored To Postpartum Needs And Challenges, Will Be Taught By The Researcher And The Team’s Psychologist. The Topics Of Sessions One Through Eight Are As Follows: Introduction And Treatment Guidelines, Behavioral Change And Mindfulness, Acceptance And Values, Values Clarification, Cognitive Defusion, Committed Action, Acceptance With Suffering, And Conclusion And Wrap-Up. For Each Session, Related Homework Assignments Will Be Given, And Their Completion Will Be Reviewed By The Researcher In Subsequent Sessions. It Should Be Noted That Prior To The Intervention, Participants Will Complete The Study’s Questionnaires As A Pretest, And Ten Days After The Final Session, They Will Complete The Same Instruments As A Posttest To Enable The Comparison And Analysis Of Pre- And Posttest Scores.
Category
Treatment - Other

2

Description
Control group: During The 8-Week Intervention Period For The Intervention Group, The Control Group Will Not Receive Any Additional Intervention And Will Continue Their Routine Activities Without Participating In The Intervention Sessions Conducted By The Research Team. Before The Intervention Begins, Participants In The Control Group Will Also Complete The Research Questionnaires As A Pre-Test. Then, Ten Days After The Final Session, They Will Complete The Same Instruments As A Post-Test In Order To Allow For Comparison And Analysis Of Pre- And Post-Test Scores. In Observance Of The Right To Access Treatment, After Completing The Final Questionnaire, Audio Files Of The Sessions Will Be Provided Free Of Charge To All Members Of The Control Group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Comprehensive Health Services Center No. 4 (Manzariyeh)
Full name of responsible person
Mehraban Sadeghi
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Comprehensive Health Services Center No. 4, Karim Bayati Street, Manzariyeh Neighborhood
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Shahrekord University of Medical Sciences
Grant code / Reference number
7995
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahrekord 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
Shahre-kord University of Medical Sciences
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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