Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Acceptance and Commitment Therapy- based Sexual Health on Body Image Acceptance and Sexual Well-Being in Primiparous Women after Childbirth

Protocol summary

Study aim

The Effect of Acceptance and Commitment Therapy-based Sexual Health on Body Image Acceptance and Sexual Well-Being in Primiparous Women after Childbirth

Design

A randomized controlled clinical trial with a parallel-group design and no blinding was conducted on 120 patients. Randomization was performed using R software.

Settings and conduct

Participants were recruited via random sampling from the Comprehensive Health Service Centers. This study is an unblinded clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria - Age 18 to 40 years - First childbirth experience - At least 6 weeks and at most 6 months since delivery - Active marital cohabitation with the spouse - Informed consent to participate in the study - No severe mental disorder based on the health record - Planned pregnancy - No history of infertility - No symptoms of depression, based on the Edinburgh Depression Questionnaire score - No use of psychiatric or hormonal medications affecting sexual function Exclusion criteria - Subsequent pregnancy during the study period - Absence from more than one counseling session - Participation in similar interventions during the study period - Withdrawal from the study at any stage

Intervention groups

Participants in the intervention group will receive Sexual Acceptance and Commitment Therapy (Sexual ACT) over four weekly 90-minute group counseling sessions. The sessions will encompass mindfulness training, acceptance of internal experiences, identification of personal values, commitment to value-based action, and restructuring of attitudes toward body image and sexual relationships.

Main outcome variables

Body Image Acceptance and Sexual Well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260607069679N1**
Registration date: **2026-06-17, 1405/03/27**
Registration timing: **prospective**

Last update: **2026-06-17, 1405/03/27**
Update count: **0**

Registration date

2026-06-17, 1405/03/27

Registrant information

Name

Mohadese Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6730

Email address

mohadeseamiri028@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-11, 1405/04/20

Expected recruitment end date

2026-11-11, 1405/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Acceptance and Commitment Therapy-based Sexual Health on Body Image Acceptance and Sexual Well-Being in Primiparous Women after Childbirth

Public title
The Effect of Acceptance and Commitment Therapy-based Sexual Health on Body Image Acceptance and Sexual Well-Being in Primiparous Women after Childbirth

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 40 years Primiparous women (first childbirth experience) At least 6 weeks and at most 6 months postpartum Being in an active marital/sexual relationship with the spouse Willingness to participate in the study and providing informed consent No severe mental disorder based on the health record Planned/wanted pregnancy No history of infertility No signs of depression (based on the Edinburgh questionnaire score) No use of psychiatric medications or hormonal medications affecting sexual function

Exclusion criteria:
Becoming pregnant again during the study Absence from more than one counseling session Participation in similar interventions during the study period Withdrawal from further cooperation at any stage of the study

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method, parallel unit of randomization, the blockrand statistical package in R software will be used to generate the allocation sequence, no blinding.

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 Mashhad University of Medical Sciences

Street address
Ferdowsi University of Mashhad Campus, East Entrance, Azadi Square, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2026-04-27, 1405/02/07

Ethics committee reference number
IR.MUMS.NURSE.REC.1405.004

Health conditions studied

1

Description of health condition studied
Body Image Acceptance and Sexual Well-Being

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Body Image Acceptance

Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention

Method of measurement
Body Image–Acceptance and Action Questionnaire: BI-AAQ,Female Sexual Well-Being Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, participants will receive Sexual Acceptance and Commitment Therapy (Sexual ACT) through four weekly 90-minute group counseling sessions.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Service Centers
Full name of responsible person
Rahele Babazade
Street address
Ferdowsi University of Mashhad Campus, East Entrance, Azadi Square
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 992 340 8252
Email
mohadeseamiri028@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Neyshabour University of Medical Sciences
Full name of responsible person
Rahele Babazade
Street address
Kharazmi Educational Complex, Ferdowsi University of Mashhad Campus, East Entrance, Azadi Square
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 992 340 8252
Email
mohadeseamiri028@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
university

Proportion provided by this source
20

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
Mohadese Amiri
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Kharazmi Educational Complex, Ferdowsi University of Mashhad Campus, East Entrance, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
051433339273
Email
mohadeseamiri028@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohadese Amiri
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Kharazmi Educational Complex, Ferdowsi University of Mashhad Campus, East Entrance, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3884 6730
Fax
Email
mohadeseamiri028@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohadese Amiri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Kharazmi Educational Complex, Ferdowsi University of Mashhad Campus, East Entrance, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3884 6730

Fax

Email

mohadeseamiri028@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information related to the primary outcome and related measures may be shared.

When the data will become available and for how long

Access to the data will begin 6 months after the publication of the results

To whom data/document is available

Graduate students and researchers

Under which criteria data/document could be used

The information will be made available to individuals conducting research in this field or related topics, if necessary, while preserving the authors' rights and publication rights.

From where data/document is obtainable

Mohadese Amiri mohadeseamiri028@gmail.com 09923418252

What processes are involved for a request to access data/document

Upon receiving the request, it will be reviewed and discussed with the research team, and a response will be provided to the applicant.

Comments