Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Acceptance and Commitment Therapy (ACT) on Sexual Function and Sexual Satisfaction in Pregnant Women: A Randomized Clinical Trial

Protocol summary

Study aim

To determine the effectiveness of Acceptance and Commitment Therapy (ACT) on sexual function in pregnant women.

Design

This study will be a randomized controlled trial with a parallel-group design. Participants will be randomly allocated to the two groups (1:1) using the RAND function in Excel, with allocation concealment maintained. Assessments will be conducted at baseline, post-intervention, and two-month follow-up. The study will be single-blind, with the outcome analyst blinded to group allocation. Participant blinding will not be possible due to the nature of the intervention.

Settings and conduct

The study will be conducted in Torbat-e Heydariyeh, Iran. Participants will be recruited from comprehensive health centers, gynecology clinics, and midwifery counseling centers. The intervention sessions will be delivered online via the Skyroom platform.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Singleton pregnancy without serious medical complications Gestational age between 12 and 24 weeks at enrollment. Access to the internet and a smart device to participate in online sessions Willingness and ability to attend all intervention sessions. Absence of severe or persistent psychiatric disorders. Provision of written informed consent. Exclusion criteria: pregnancy complications, withdrawal, absence from >1 session.

Intervention groups

Intervention Group: Participants will receive Acceptance and Commitment Therapy (ACT) in four weekly online group sessions of 90 minutes. Content includes acceptance of unpleasant thoughts and emotions, mindfulness exercises, cognitive defusion, self-as-context, values clarification, and committed actions. Homework will be assigned for each session. Control Group: Participants in this group will receive no psychological or online intervention. They will only receive routine prenatal care and standard educational services provided at health-care centers.

Main outcome variables

Sexual function of pregnant women measured using the total score of the Female Sexual Function Index (FSFI).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260205068766N1**
Registration date: **2026-05-23, 1405/03/02**
Registration timing: **prospective**

Last update: **2026-05-23, 1405/03/02**
Update count: **0**

Registration date

2026-05-23, 1405/03/02

Registrant information

Name

Mohadese Adeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.mohadese.adeli@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date
2027-02-20, 1405/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Acceptance and Commitment Therapy (ACT) on Sexual Function and Sexual Satisfaction in Pregnant Women: A Randomized Clinical Trial

Public title
The Effect of Acceptance and Commitment Therapy on Sexual Function and Sexual Satisfaction in Pregnant Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Singleton pregnancy without serious medical complications Gestational age between 12 and 24 weeks at enrollment. Access to the internet and a smart device to participate in online sessions Willingness and ability to attend all intervention sessions. Absence of severe or persistent psychiatric disorders. Provision of written informed consent.
Exclusion criteria:
Occurrence of any serious pregnancy complications during the study. Withdrawal from the study. Absence from more than one intervention session.
Age
No age limit
Gender
Female

Phase
0
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining written informed consent, participants will be randomly allocated to the intervention and control groups using simple randomization based on a random numbers table. The randomization process will be performed by an independent person.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the psychological nature of the intervention, blinding of participants and therapists is not feasible. However, data analysis will be performed by a blinded statistician who is unaware of group allocation (single-blind).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ToTorbat Heydariyeh University of Medical Sciences
Street address
Torbat Heydarieh University of Medical Sciences, Gharani 1 St., Torbat Heydarieh, Khorasan Razavi, Iran.
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Torbat Heydariyeh
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Razavi Khorasan
Postal code
9516915169
Approval date
2026-01-18, 1404/10/28
Ethics committee reference number
IR.THUMS.REC.1404.042

Health conditions studied

1

Description of health condition studied
Sexual function and satisfaction problems in pregnant women
ICD-10 code
Z34
ICD-10 code description
Encounter for supervision of normal pregnancy

Primary outcomes

1

Description
Sexual function of pregnant women will be measured using the total score of the Female Sexual Function Index (FSFI).
Timepoint
Baseline: one day before the intervention Post-intervention: immediately after completion of the intervention Follow-up: two months after the intervention
Method of measurement
The FSFI questionnaire will be completed online, and the total sexual function score will be calculated.

Secondary outcomes

1

Description
Sexual satisfaction of pregnant women will be measured using the Larson Sexual Satisfaction Questionnaire.
Timepoint
Baseline: one day before the intervention Post-intervention: immediately after completion of the intervention Follow-up: two months after the intervention
Method of measurement
The Larson Sexual Satisfaction Questionnaire will be completed online.

Intervention groups

1

Description
Intervention group: Participants in this group will receive Acceptance and Commitment Therapy (ACT) in an online group format via Skyroom in 4 weekly sessions of 90 minutes. Session content will include acceptance of unpleasant thoughts and emotions, mindfulness, cognitive defusion, self-as-context, values clarification in marital relationships, and committed actions to improve sexual function and sexual satisfaction. Homework will be assigned for each session.
Category
Treatment - Other

2

Description
Control group: Participants in this group will receive no psychological or online intervention and will only receive routine prenatal care and standard education at health centers.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urban and rural comprehensive health centers, Torbat-e Heydarieh, Iran
Full name of responsible person
Dr. Mohadese Adeli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Dr.Maryam Kabiriyan
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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
Torbate-Heidaria 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
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Dr.Mohadese Adeli
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the sensitive nature of the study topic and the need to protect participants' confidentiality, individual participant data (IPD) will not be shared.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available