Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of acceptance and commitment therapy on changing the decision of pregnant women seeking abortion to continue their pregnancy, acceptance of the maternal role and adaptation to pregnancy

Protocol summary

Study aim

To determine the effect of Acceptance and Commitment Therapy on changing the decision of pregnant women seeking abortion to continue their pregnancy, acceptance of the maternal role, and adaptation to pregnancy.

Design

This is a randomized controlled clinical trial with two parallel groups and no blinding, with an anticipated sample size of 112 participants (56 per group). Participants will be allocated using block randomization with blocks of six and a 1:1 allocation ratio. The randomization sequence will be generated by an independent individual, and allocation will be concealed using opaque, sealed, sequentially numbered envelopes. Study phase: Not applicable.

Settings and conduct

This randomized controlled clinical trial will be conducted at the Nafas Center in Ahvaz. After obtaining informed consent, participants will be randomly allocated to the intervention and control groups. The intervention group will receive 8 weekly 90-minute sessions of acceptance and commitment therapy (ACT)-based education, while the control group will receive routine services provided by the center. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion: Women 18–48y, 4–20wks gestation, intrauterine pregnancy, Persian literacy, consent; Exclusion: acute psych/med/obstetric conditions, pregnancy/fetal complications, substance abuse, major stressors, concurrent psychotherapy, incomplete data.

Intervention groups

Intervention group: Group-based acceptance and commitment therapy (ACT) education will be provided in 8 weekly 90-minute sessions, delivered in 6 groups. The control group will receive routine services at the Nafas Center in Ahvaz, including routine prenatal care and psychosocial support, and will not receive the ACT intervention.

Main outcome variables

Change in the decision to continue pregnancy; acceptance of the maternal role; adaptation to pregnancy

General information

Reason for update

Due to a technical issue with the IRCT system, the registration and approval process of the study was delayed. As a result, the participant recruitment start date entered when initially completing the registration form does not correspond to the final approval date of the study. Since participant recruitment has not yet started, I would like to correct the participant recruitment start date registered in the system so that it accurately reflects the actual status of the study and is consistent with the approval date of the clinical trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20260719070262N1**
Registration date: **2026-09-18, 1405/06/27**
Registration timing: **prospective**

Last update: **2026-09-27, 1405/07/05**
Update count: **1**

Registration date

2026-09-18, 1405/06/27

Registrant information

Name

Shafa Rahmani Tabar

Name of organization / entity

Country
Iran (Islamic Republic of)
Phone
+98 916 619 9850
Email address
shafa823@gmail.com

Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-10, 1405/07/18
Expected recruitment end date
2027-01-20, 1405/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of acceptance and commitment therapy on changing the decision of pregnant women seeking abortion to continue their pregnancy, acceptance of the maternal role and adaptation to pregnancy

Public title
The Effect of an Acceptance and Commitment Therapy-Based Counseling Program on the Decision to Continue Pregnancy and Psychological Adaptation to Pregnancy among Pregnant Women Seeking Abortion
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women of reproductive age aged 18 to 48 years gestational age of 4 to 20 weeks confirmed intrauterine pregnancy literacy in reading and writing in Persian provision of written informed consent
Exclusion criteria:
Presence of acute psychiatric disorders Presence of medical or obstetric complications Presence of acute pregnancy complications, such as bleeding or threatened abortion Fetal abnormalities Addiction to alcohol, illicit drugs, or other psychotropic substances Occurrence of significant stressful life events, such as the death of a spouse or a family member Concurrent participation in a similar psychotherapy program Failure to complete the study questionnaires
Age
From **18 years** old to **48 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to two groups using block randomization with blocks of six and a 1:1 allocation ratio: an acceptance and commitment therapy-based counseling group (n = 56) and a control group (n = 56). The randomization sequence will be generated using blocks of six by an individual independent of the research team. To ensure allocation concealment, each allocation will be placed separately in an opaque, sealed, light-proof, sequentially numbered envelope, with only one allocation code (A or B) inside each envelope. After eligibility criteria have been confirmed and informed consent has been obtained, the next envelope will be opened in sequential numerical order, and the participant will be assigned to either the intervention or control group according to the allocation code contained in the envelope.
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 Ahvaz University of Medical Sciences
Street address
Golestan Blvd., Ahvaz University of Medical Sciences, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6166654181
Approval date
2026-07-25, 1405/05/03
Ethics committee reference number
IR.AJUMS.REC.1405.189

Health conditions studied

1

Description of health condition studied
unwanted pregnancy
ICD-10 code
Z64.0

ICD-10 code description
Problems related to unwanted pregnancy

Primary outcomes

1

Description
Score of change in the decision of pregnant women seeking abortion to continue the pregnancy and acceptance of pregnancy based on the Lederman Prenatal Self-Evaluation Questionnaire (PSEQ)
Timepoint
Measurement of the score of change in the decision of pregnant women seeking abortion to continue the pregnancy and acceptance of pregnancy using the Lederman Prenatal Self-Evaluation Questionnaire (PSEQ) at baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and one month after the end of the intervention (follow-up).
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

Secondary outcomes

1

Description
Maternal role acceptance (maternal role identification) score based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
Measurement of the score of maternal role acceptance (identification with the maternal role) using the Lederman Prenatal Self-Evaluation Questionnaire at baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and one month after the end of the intervention (follow-up).
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

2

Description
Score of relationship with the partner based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
Measurement of the score of relationship with the partner using the Lederman Prenatal Self-Evaluation Questionnaire at baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and one month after the end of the intervention (follow-up).
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

3

Description
Score of preparation for childbirth based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
At baseline (before the start of the intervention), immediately after completion of the 8 intervention sessions, and one month after the end of the intervention.
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

4

Description
Score of sense of control during the childbirth process based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
At baseline (before the start of the intervention), immediately after completion of the 8 intervention sessions, and one month after the end of the intervention.
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

5

Description
Score of well-being of self and baby based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
At baseline (before the start of the intervention), immediately after completion of the 8 intervention sessions, and one month after the end of the intervention.
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

6

Description
Score of relationship with mother based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
At baseline (before the start of the intervention), immediately after completion of the 8 intervention sessions, and one month after the end of the intervention.
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

7

Description
Score of adaptation to pregnancy based on the Lederman Prenatal Self-Evaluation Questionnaire
Timepoint
At baseline (before the start of the intervention), immediately after completion of the 8 intervention sessions, and one month after the end of the intervention.
Method of measurement
Lederman Prenatal Self-Evaluation Questionnaire

8

Description
Score of psychological adaptation to pregnancy based on

the Lederman Prenatal Self-Evaluation Questionnaire

Timepoint

At baseline (before the start of the intervention), immediately after completion of the 8 intervention sessions, and one month after the end of

Method of measurement

Lederman Prenatal Self-Evaluation Questionnaire

Intervention groups

1

Description

Intervention group: Group-based Acceptance and Commitment Therapy (ACT) delivered in 8 weekly 90-minute sessions, conducted in 6 groups of 8–9 participants, aiming to improve psychological adaptation to pregnancy, maternal role acceptance, and decision-making regarding continuation of pregnancy. The sessions will cover introduction to ACT, acceptance, cognitive defusion, self-as-context, present-moment awareness, values, and committed action.

Category

Treatment - Other

2

Description

Control group: Participants will receive routine services provided by Nafas Center, including routine prenatal care and usual psychosocial support. The control group will not receive ACT during the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nafas Center, East Ahvaz

Full name of responsible person

Somayeh Ghobaiti

Street address

Rastgari Street, Si Metri, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6187653599

Phone

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Email

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2

Recruitment center

Name of recruitment center

Nafas Center, West Ahvaz

Full name of responsible person

Laleh Jafari

Street address

Kamplo, Enghelab St., Corner of Shahid Hatef St., Opposite District 6 Municipality

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Province

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Postal code

6187653599

Phone

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Email

somayehghobeyty@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Abdollah Rafiei

Street address

Jundishapur University of Medical Sciences in Ahvaz, Golestan Boulevard, opposite the Water and Electricity Organization

City

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Province

Khouzestan

Postal code

6135715794

Phone

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Email

info@ajums.ac.ir

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
Shafa Rahmanitabar

Position
Master's Student in Midwifery Counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Ahvaz, Golestan, Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, Faculty of Nursing and Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mina Eirvani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Golestan, Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, Faculty of Nursing and Midwifery

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Person responsible for updating data

Contact

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Position
Master's Student in Midwifery Counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Golestan, Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, Faculty of Nursing and Midwifery

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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 need to maintain the confidentiality of participants' information and the limitations arising from informed consent and ethical considerations of the study, de-identified individual participant data will not be shared with other researchers.

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
Not applicable

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available