Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of group counseling based on dialectical behavior therapy compared to a control group on stress and sexual quality of life of pregnant women with a history of failed pregnancy: A randomized clinical trial

Protocol summary

Study aim
To assess the effect of group counseling based on dialectical behavior therapy compared to a control group on stress and sexual quality of life of pregnant women with a history of failed pregnancy

Design
This is a randomized clinical trial with a control group with parallel groups without blinding, in which 76 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Comprehensive Health Centers in Hamadan, involving 76 eligible pregnant women with a history of failed pregnancy. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 45 years, Gestational age 12 to 20 weeks, Pregnant woman with a history of failed pregnancy, Being literate, Exclusion criteria: Drug addiction, Mental and psychiatric disorder, Neurological disease

Intervention groups
Intervention group: Routine prenatal care plus group counseling sessions based on dialectical behavior therapy for 60 to 75 minutes, once a week for 6 weeks (including basic concepts of mindfulness and the chain model Control group: Routine prenatal care

Main outcome variables
Primary outcome: Mean stress score; Mean sexual quality of life score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N619**
Registration date: **2026-07-25, 1405/05/03**
Registration timing: **prospective**

Last update: **2026-07-25, 1405/05/03**
Update count: **0**

Registration date
2026-07-25, 1405/05/03

Registrant information
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Name of organization / entity
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of group counseling based on dialectical behavior therapy compared to a control group on stress and sexual quality of life of pregnant women with a history of failed pregnancy: A randomized clinical trial

Public title
Effect of group counseling based on dialectical behavior therapy compared to a control group on stress and sexual quality of life of pregnant women with a history of failed pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 45 years, Gestational age 12 to 20 weeks, Pregnant woman with a history of failed pregnancy, Being literate,
Exclusion criteria:
Drug addiction, Mental and psychiatric disorder, Neurological disease

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695

Approval date
2026-07-25, 1405/05/03

Ethics committee reference number
IR.UMSHA.REC.1405.291

Health conditions studied

1

Description of health condition studied
Perceived stress

ICD-10 code
F43

ICD-10 code description
Reaction to severe stress, and adjustment disorders

Primary outcomes

1

Description
Mean perceived stress score

Timepoint
Before intervention and 6 weeks after

Method of measurement
Using the Cohen Perceived Stress Questionnaire

2

Description
Mean sexual quality of life score

Timepoint
Before intervention and 6 weeks after

Method of measurement
Using the Sexual Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine prenatal care plus group

counseling sessions based on dialectical behavior therapy for 60 to 75 minutes, once a week for 6 weeks (including basic concepts of mindfulness and the chain model (stimulus, thoughts, emotion, physical response, behavior, and consequences), distress tolerance skills with special emphasis on managing thoughts related to the experience of a failed pregnancy, emotional regulation skills, identifying and naming emotions with an emphasis on non-sexual intimacy, effective communication skills, requesting support and co-regulation in the marital relationship, designing an immediate action plan to manage stressful situations, strengthening motivation to continue practicing and planning to maintain skills in the postpartum period, in all sessions, practical mindfulness exercises, radical acceptance, emotion regulation, and homework are continuously followed up.)

Category

Treatment - Other

2

Description

Control group: Routine prenatal care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan

Full name of responsible person

Fatemeh Arianfar

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

Fatemeh Arianfar

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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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