Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The Effect of Cognitive-Behavioral Therapy Based on Mindfulness on Concerns of Nulliparous Adolescent Pregnant Women

Protocol summary

Study aim

1_the effect of cognitive behavioral counseling based on mindfulness on anxiety about birth and newborn in nulliparous adolescents 2_the effect of cognitive behavioral counseling based on mindfulness on concerns about weight and body image in nulliparous adolescents 3_the effect of cognitive behavioral counseling based on mindfulness on anxiety about emotions and relationships in nulliparous adolescents

Design

A clinical trial with two intervention and control groups, without blinding, simple randomization, the intervention was conducted during 8 sessions on 66 people in the intervention group.

Settings and conduct

After identifying the pregnant adolescents with primiparous children in Kot Abdullah and Kayan health centers, if they met the criteria for participation in the study, the purpose of the research was explained to them. They were placed in two intervention and control groups. Both groups completed the pre-test and then 8 sessions of cognitive-behavioral counseling based on mindfulness were held for the intervention group during 8 weeks, and after the intervention, both groups completed the post-test.

Participants/Inclusion and exclusion criteria

Married teenagers who are first born and have a high anxiety score based on pregnancy anxiety questionnaire, if they wish, will enter the study after filling out a written consent form. Confirmed physical and mental problems in themselves or their spouse are the exclusion criteria for this study.

Intervention groups

The intervention group receives 8 sessions of 90-minute cognitive-behavioral counseling based on mindfulness, once a week, and finally its effect on concerns during pregnancy is evaluated.

Main outcome variables

Reducing concerns during pregnancy in nulliparous adolescents

General information

Reason for update

The sampling date was changed

Acronym

IRCT registration information

IRCT registration number: **IRCT20250106064287N1**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **prospective**

Last update: **2025-02-05, 1403/11/17**
Update count: **2**

Registration date

2025-01-08, 1403/10/19

Registrant information

Name
Fatemeh Fakharzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
fakharzadeh.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-08-22, 1404/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Cognitive-Behavioral Therapy Based on Mindfulness on Concerns of Nulliparous Adolescent Pregnant Women

Public title
Concerns during pregnancy of Nulliparous Adolescent

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
marriage Adolescent 10 to 19 years old first pregnancy Gestational age of 20 weeks and above Reading and writing literacy High score based on pregnancy concerns questionnaire

Exclusion criteria:
Existence of severe physical problems Having a history of mental illness confirmed by a psychiatrist in yourself or your spouse Participation in other psychological training and counseling programs Existence of high-risk conditions (diabetes mellitus and high blood pressure, etc.)

Age
From **10 years** old to **19 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible people will be selected for the study by available sampling method and then the participants will be divided into intervention and control groups using simple randomization method. The randomization method used in this study is the use of a table of random numbers. The table of random numbers is a collection of numbers that are generated without a specific pattern or order and completely randomly, and turned into a table. At first, the direction of reading numbers from the table was determined. The direction of reading numbers from the table of random numbers in this study. is from the left side, then the even numbers extracted from the table were assigned to the intervention group and the odd numbers extracted from the table were assigned to the control group. Each group consists of 33 participants.In this study, due to the nature of the interventions, it is practically not possible for the participants and the researcher to be blinded due to the knowledge of the participants about being in the intervention group and the training of the content of the sessions by the researcher, but the concealment of the random allocation by a central method and by another person will take place This ensures that there will be no bias in the selection of intervention and control groups and that the effects of the intervention will be evaluated accurately and fairly. Blinding (according to the researcher) Not blinded

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 Jundishapur University of Medical Sciences

Street address
Golestan Blvd., Esfand St., Jundishapur University of Medical Sciences, Ahvaz

City
ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2024-12-21, 1403/10/01

Ethics committee reference number
IR.AJUMS.REC.1403.515

Health conditions studied

1

Description of health condition studied
Concerns during pregnancy

ICD-10 code
R45.82

ICD-10 code description
Worries

Primary outcomes

1

Description
Concerns during pregnancy

Timepoint
Before the start of the intervention, immediately after the end of the intervention sessions, 4 weeks after the end of the intervention

Method of measurement
Prenatal Distress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, 8 cognitive-behavioral counseling sessions based on mindfulness will be held during 8 90-minute sessions. In order to evaluate the results of the treatment, relevant questionnaires will be completed by the participants before the intervention, immediately after the intervention, and 4 weeks after the intervention. and will be used for statistical analysis

Category
Treatment - Other

2

Description
Control group: Control group: will receive usual care. In order to evaluate the treatment results, relevant questionnaires will be completed by the participants before the intervention, immediately after the intervention and 4 weeks after the intervention and will be used for statistical analysis

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kot Abdullah Karun Health Center
Full name of responsible person
Fatemeh Fakharzadeh
Street address
Next to Sina Hospital-Ayatollah Behbahani Blvd-Ahvaz - Karun (Kut Abdollah)
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2

Recruitment center
Name of recruitment center
Kian Abad Health Center
Full name of responsible person
Fatemeh Fakharzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Ground floor,Research and Technology Vice-Chancellor of Ahvaz Jundishapur University of Medical Sciences and Health Services,Ahvaz Jundishapur University of Medical Sciences,Golestan St,Ahvaz,Iran
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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
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

Mitra Tadayon Najafabadi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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student

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data of the study are classified and coded so that the names of the people cannot be identified

When the data will become available and for how long
Access to the study data is possible after the results are published in the journal

To whom data/document is available
All people who want to use the data in this field can access the study data

Under which criteria data/document could be used
Study data can be used for comparison with other results

From where data/document is obtainable
Mrs. Mitra Tedin Najafabadi, a member of the academic faculty of Jundishapur University of Ahvaz
mitratadayon2000@yahoo.com

What processes are involved for a request to access data/document
The request is sent by e-mail to the person in charge of the scientific or general responsibility of the study

Comments