

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of Mindfulness-based Cognitive Behavioral Therapy on Fear of childbirth in Teenage Primigravida Women

Protocol summary

Study aim

Determining the effect of Mindfulness-based Cognitive Behavioral Therapy on Fear of childbirth in Teenage Primigravida Women

Design

A randomized controlled clinical trial with parallel groups, Randomized using block randomization method. Sample size will be 112 (56 persons per group)

Settings and conduct

The place of the study is the healthcare centers of Shush city. The study population is teenage primigravida women. Blinding is not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: conditions: age range 13-19 years; pregnancy age 28 weeks; low-risk pregnancy; and singleton. Non-inclusion criteria: history of receiving mindfulness training; facing major stress due to unforeseen events; addiction to alcohol, narcotics and other psychoactive drugs.

Intervention groups

In the control group, there is no intervention. In the intervention group, the method of mindfulness based cognitive behavioral therapy is used.

Main outcome variables

Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230716058809N1**

Registration date: **2023-07-30, 1402/05/08**

Registration timing: **prospective**

Last update: **2023-07-30, 1402/05/08**

Update count: **0**

Registration date

2023-07-30, 1402/05/08

Registrant information

Name

Leila Hasanvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 4262 6955

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leilahasanvand2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mindfulness-based Cognitive Behavioral Therapy on Fear of childbirth in Teenage Primigravida Women

Public title

The effect of Mindfulness-based Cognitive Behavioral Therapy on Fear of childbirth

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 13-19 years Primigravida women Gestation age 28 weeks Literacy for reading and writing Singleton

pregnancy Low risk pregnancy Obtaining a moderate to severe fear of childbirth score (score 38-84 from Vijma questionnaire version A) Informed willingness to participate in research

Exclusion criteria:
History of receiving mindfulness training Facing major stress caused by unforeseen events Addiction to alcohol, drugs and other psychoactive drugs

Age
From **13 years** old to **19 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
For random allocation, considering that we have two intervention and control groups, we will use a block of size 4. In order to determine the allocation sequence using the block randomization method, random allocation sequence generation software will be used. In order to hide the sequence of allocation, the papers identifying the group of people are placed inside the envelopes in the opaque package and coded in the same order.

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
Deputy of Research and Technology, Esfand Ave., Golestan Blvd.

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2023-07-08, 1402/04/17

Ethics committee reference number
IR.AJUMS.REC.1402.226

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of childbirth

Timepoint

The beginning of the study (pre-test), the end of the study (post-test), 1 month after the last session.

Method of measurement

Vijma standard fear of childbirth questionnaire version A and version B

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teenage primigravida women receiving mindfulness-based cognitive behavioral therapy. Mindfulness-based cognitive behavioral therapy (MBCT) is an approach to psychotherapy that uses cognitive behavioral therapy (CBT) methods along with mindfulness meditation practices and similar psychological strategies. In MBCT, mindfulness is based on 4 principles including Body awareness (body position and body movement/activity), body sensations (including those related to emotions), mental states (including emotional states) and mental content (thoughts, images) are taught. Before starting the treatment program, the training certificate of the MBCT course will be received and attached to the study, then the cognitive therapy program based on mindfulness for fertility attitude in the form of an 8-session program during 8 weeks by the researcher will be presented. Meetings will be held in groups. Contents and assignments will be presented to the people of the intervention group on a weekly basis. It will be considered that the participants, whenever they have a problem in doing the assignments, have more interaction with the researcher in person or virtually to ensure the correctness of the assignments.

Category

Treatment - Other

2

Description

Control group: Teenage primigravida women, for whom no intervention is performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shush City Health Center

Full name of responsible person

Amin Hejazi

Street address

In front of the post office; Saat square

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Shush

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6135715794

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+98 61 3373 8331

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khz-healthcenter@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sahand Jorfi

Street address

Deputy of research and technology, Esfand Ave.,
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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

Mina Iravani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

All data and results of the research will be provided to Ahvaz Jundishapur University of Medical Sciences

When the data will become available and for how long

It will be possible to access the research documents six months after the final statistical analysis.

To whom data/document is available

The data will be available only for the use of researchers of academic institutions

Under which criteria data/document could be used

In order to conduct similar research

From where data/document is obtainable

In order to receive the data, people can refer to the main executive of the project, Dr. Mina Iravani, a member of the academic staff of Jundishapur University of Medical Sciences, Ahvaz.

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

After obtaining the necessary permits from the Jundishapur University of Medical Sciences and the Vicechancellor of Research and Technology of this university, the applicant can proceed to receive the documents.

Comments