Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness-based cognitive-behavioral therapy on fertility attitude in single-child working women

Protocol summary

Study aim
The effect of mindfulness-based cognitive behavioral therapy on childbearing attitudes in single-child working women

Design
The clinical trial has a randomized control group, an intervention and a control group of 36 people each, randomization by 4 blocks method.

Settings and conduct
The place of the study is the health center in the east of Ahvaz city. The sample of the research is working women with one child referring to the health center who meet the conditions to entering the study. The participants are randomly assigned to two control and intervention groups. In the control group, there is no intervention, and in the intervention group, the method of cognitive behavioral therapy based on mindfulness (MBCT) is used. The treatment program will be provided by the researcher in the form of an 8-session program over 8 weeks. Meetings will be held in groups. Contents and assignments will be presented to the intervention group on a weekly basis. The way to follow up the samples in 3 stages is to fill the questionnaire in the first session (pre-test), the last session (post-test) and one month after the last training session.

Participants/Inclusion and exclusion criteria
Entry conditions: being married; being between the ages of 18 and 44 years old 3; reading and writing literacy; working women; single-child women. Conditions for non-entry: having a child with a disability; secondary infertility of a woman or her husband; having a serious physical illness that prevents fertility.

Intervention groups
Participants are randomly assigned to two control and intervention groups. In the control group, there is no intervention, and in the intervention group, the method of mindfulness based cognitive behavioral therapy (MBCT) is used.

Main outcome variables
Childbearing attitude

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230710058735N1**
Registration date: **2023-07-18, 1402/04/27**
Registration timing: **prospective**

Last update: **2023-07-18, 1402/04/27**
Update count: **0**

Registration date
2023-07-18, 1402/04/27

Registrant information
Name
Mitra Ahmadfakhrodin
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 3224 7361
Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-06, 1402/05/15

Expected recruitment end date
2024-02-04, 1402/11/15

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 fertility attitude in single-child working women

Public title
The effect of mindfulness-based cognitive-behavioral therapy on fertility attitude's women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being married Single-child women Literacy for reading and writing Having the age of 18 to 44 years Employment of women Low score based on attitude towards Childbearing questionnaire: less than 11

Exclusion criteria:
Secondary infertility of wife or husband Having mental disorders in a woman or her husband Having a serious physical illness that prevents fertility Husband's activity in jobs that require periodic migration. Having a child with a disability

Age
From **18 years** old to **44 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

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 4. In order to determine the allocation sequence using the 4 block 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., Ahvaz, Iran

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2023-06-24, 1402/04/03

Ethics committee reference number
IR.AJUMS.REC.1402.195

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fertility Attitude Score in Fertility Attitude Questionnaire

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

Method of measurement
Fertility Attitude Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single-child working 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. In this study, the participants who meet the study entry criteria are randomly assigned to two control

and intervention groups. In the control group, there is no intervention, and in the intervention group, the method of cognitive therapy based on mindfulness (MBCT) is used. 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. How to follow up the samples in 4 steps by filling out the questionnaire The first session (pre-test), the last session (post-test),and one month after the last session after the last training session.

Category

Treatment - Other

2

Description

Control group: Single-child working women without receiving cognitive behavioral therapy based on mindfulness

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

East Ahvaz Health Center

Full name of responsible person

Amralah Mardani

Street address

in front of Haft Tir Park - Shahid Rostagari street - Ayatollah Behbahani highway

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+98 61 3373 8331

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info@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., Golestan Blvd., 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 scientific

inquiries

Contact

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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 Jundishapur University of Medical Sciences Ahvaz

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 promote childbearing

From where data/document is obtainable
In order to receive the data, people can refer to the main executive of the project, Mitra Tadayon Najafabadi, 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