

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of cognitive counseling based on mindfulness (MBCT) on psychological well-being and choosing the type of delivery in pregnant women who referred to childbirth preparation classes at Ayatollah Taleghani Hospital in Ilam city in 2023

Protocol summary

Study aim

Investigating the effect of Mindfulness Based Cognitive Therapy (MBCT) on psychological well-being and choosing the type of delivery in pregnant women who referred to childbirth preparation classes

Design

The clinical trial has a control group, single-blind, randomized groups using Random Allocation Software.

Settings and conduct

The current research is a randomized controlled clinical trial (RCT) in which pregnant women referring to Ayatollah Taleghani Hospital in Ilam between October and December 2023 will participate, after obtaining the necessary permits and code of ethics From Ilam University of Medical Sciences, the plan will be registered in the clinical trials system and the RCT code will be obtained.

Participants/Inclusion and exclusion criteria

The age of the participant is between 20 and 40 years, the gestational age is more than 20 weeks, the mother is not addicted to drugs, the absence of abortion symptoms, the absence of hypertension or diabetes. Exit criteria: withdrawal of the participant and absence or not completing the sessions completely.

Intervention groups

While the control group will only receive regular pregnancy care, the experimental group will receive MBCT program training and attendance at pregnancy preparation classes during 8 sessions, each session lasting 90 minutes (twice a week).

Main outcome variables

Choosing the type of delivery; Psychological well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221116056514N1**

Registration date: **2023-07-27, 1402/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-27, 1402/05/05**

Update count: **0**

Registration date

2023-07-27, 1402/05/05

Registrant information

Name

Elham Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3331 4441

Email address

alizadeh.elham2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of cognitive counseling based on mindfulness (MBCT) on psychological well-being and choosing the type of delivery in pregnant women who referred to childbirth preparation classes at Ayatollah Taleghani Hospital in Ilam city in 2023

Public title
Investigating the effect of cognitive counseling based on mindfulness (MBCT) on psychological well-being and choosing the type of delivery in pregnant women who referred to childbirth preparation classes at Ayatollah Taleghani Hospital in Ilam city in 2023

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
The age of the participant is between 20 and 40 years old
The gestational age is more than 20 weeks
Absence of drug addiction in the mother
Not having abortion symptoms
Absence of high blood pressure or diabetes
Exclusion criteria:
Participant withdrawal
Absence or not completing meetings completely

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
After preparing a general list of clients, using Random Allocation Software for Clinical Trials, people are randomly selected in two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this one-way blind study, one of these groups is blinded to the intervention. Which of the groups should be blinded depends on the type of study, the sample under study or the disease in question and even the type of intervention used. In this study, the participant group was blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences
Street address
Beheshti Street, Correspondent Boulevard, next to Iran Khodro
City
Ilam
Province
Ilam
Postal code
6931975397
Approval date
2022-10-25, 1401/08/03
Ethics committee reference number
IR.MEDILAM.REC.1401.132

Health conditions studied

1

Description of health condition studied
Type of delivery
ICD-10 code
O82.1
ICD-10 code description
Delivery by emergency caesarean section

Primary outcomes

1

Description
Psychological well-being
Timepoint
Examination of psychological well-being before the intervention, 4 weeks of training (intervention), 2 weeks later re-examination
Method of measurement
After the completion of the meetings and compliance with the criteria for exiting the research during the entire process of holding the meetings, in the last stage of the research questionnaires will be distributed between both experimental and control groups and the data will be collected and analyzed in SPSS software and the results will be obtained. They will be registered.

2

Description
Choice of delivery type
Timepoint
8 sessions and each session is 90 minutes (twice a week)
Method of measurement
After the completion of the meetings and compliance with the criteria for exiting the research during the entire process of holding the meetings, in the last stage of the research questionnaires will be distributed between both experimental and control groups and the data will be

collected and analyzed in SPSS software and the results will be obtained. They will be registered.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: MBCT therapy sessions will be held according to Kabat-Zinn et al. protocol (Kabat-Zinn et al., 1992) and pregnancy preparation classes in 8 90-minute sessions (two sessions per week). 1) Description of cognitive therapy intervention sessions Behavior based on mindfulness 1) The first session of cognitive therapy based on the presence of mind, setting a general policy taking into account the aspect of confidentiality and personal life of people, inviting people to introduce themselves to each other, practicing physical examination, homework, discussion and setting weekly meetings. , the distribution of tapes and pamphlets will be. 2) The second session will include training for 14 groups of muscles, including forearms, arms, calf muscles, thighs, stomach, chest, shoulders, neck, lips, eyes, and forehead. 3) The third session Relaxed tone for six groups of muscles, including hands and arms, legs and thighs, stomach and chest, forehead and lips, and relaxed tone homework will be training. Inhaling and exhaling with relaxation and without thinking about anything else and teaching the technique of watching breathing and setting the home task of mindfulness of breathing before sleep will be dedicated. Their movements and search for physical sensations, and the homework assignment will be eating mindfulness. 6) The sixth session, training to pay attention to the mind, positive and negative thoughts, whether the thoughts are pleasant or unpleasant, allowing negative and positive thoughts to enter the mind and It will be as easy as removing them from the mind without judgment and paying deep attention to them. 7) The seventh session will include 40 minutes of sitting meditation, reviewing homework, and practicing observing the connection between activity and creation. 8) The eighth session, past materials. It will be a review and summary. 2) Description of the preparation sessions during pregnancy. The first session: In this session, which is held in the 20th to 23rd week of pregnancy, you will get to know the objectives and principles of the classes and how to conduct the classes. You will also learn about the female reproductive system and the names and functions of some organs that are involved in the process of pregnancy and childbirth, personal hygiene, adapting to the physiological changes during pregnancy. You will get to know the common complaints and how to deal with them and you will get to know the skeletal and stretching exercises, breathing and relaxation and you can do the exercises after the session. The second session: In this session, which is held during the 24th to 27th week of pregnancy, you will learn about nutrition

during pregnancy, distribution of the food pyramid, correction of posture, skeletal stretching exercises, breathing and relaxation, and after the session you can Do the exercises. Third meeting: This meeting is held in the 28th to 29th week of pregnancy. In this session, you and your wife will learn about mental health, the role of the spouse, changes in mood during pregnancy and the growth and development of the fetus, how to communicate with the fetus and correct the position of courtship, skeletal stretching exercises, breathing and relaxation, and after the session you will You can do the exercises. Fourth session: This session is held in the 30th to 31st week of pregnancy. warning signs/diagnosis of normal and abnormal pains during pregnancy, bleeding * spotting * headache * fetal movements * discharge * rupture of amniotic sac * swelling of hands and feet * correction of the position during pregnancy * skeletal and muscular exercises * in this session you will have nutrition and You will get to know maintaining a proper diet, how to take supplements, childbirth and pain reduction methods, stretching exercises, breathing and relaxed tone, and after the session you can do the exercises. Fifth session: This session is held at 32-33 weeks of pregnancy. It is possible to plan for childbirth/choose the type of childbirth/various methods of pain reduction and anesthesia in the childbirth process/choose the place of childbirth and the necessary equipment for childbirth/visiting the delivery room of a hospital if possible/correcting the situation during pregnancy/skeletal and muscular exercises / Breathing exercises and calmness of the sixth session: This session is held at 34-35 weeks of pregnancy. Familiarity with the process and symptoms of labor pain / Familiarity with the first, second and third stages of labor and how to take care of yourself in each of the stages of labor / The role of pregnancy hormones in the stages of labor / Adapting to the pain of labor / Showing a video or animation of labor / Correcting the situation in pregnancy / Skeletal and muscular exercises/breathing and relaxation exercises, seventh session: This session is held at the 36th week of pregnancy. Postpartum health and care/postpartum warning signs/postpartum grief and depression/breastfeeding training/postpartum exercises/correction of posture during pregnancy/squatting and muscle exercises/breathing and relaxation exercises Eighth session: This session is held in the 37th week of pregnancy. Baby hygiene with an emphasis on the general characteristics of the baby at birth and during the newborn period / Baby care (how to bathe and change clothes, etc.) / Breastfeeding training / Danger signs for the baby / Showing the video of breastfeeding and baby care / Modification Position in pregnancy/skeletal and muscular exercises/breathing exercises and relaxation

Category

Behavior

2

Description

Control group: Control group: The control group will receive only the usual pregnancy care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Elham Alizadeh

Street address

Shahid Beheshti St., Correspondent Blvd., next to Iran
Khodro

City

Ilam

Province

Ilam

Postal code

6931975397

Phone

+98 84 3337 2708

Email

alizadeh.elham2@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Abbas Maleki

Street address

Ilam, Bangajab, Ilam University of Medical Sciences
campus, Research and Technology Blvd

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3223 5724

Email

vcr@medilam.ac.ir

Grant name

Vice President of Research and Technology, Ilam
University of Medical Sciences

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Elham Alizadeh

Position

Midwife

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Shahid Beheshti St., Correspondent Blvd., next to Iran
Khodro

City

Ilam

Province

Ilam

Postal code

6931975397

Phone

+98 84 3337 2708

Email

alizadeh.elham2@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Elham Alizadeh

Position

midwife

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

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City

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Province

Ilam

Postal code

6931975397

Phone

+98 84 3337 2708

Email

alizadeh.elham2@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Elham Alizadeh

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Shahid Beheshti St., Correspondent Blvd., next to Iran
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City

Ilam

Province

Ilam

Postal code

6931975397

Phone

+98 84 3337 2708

Email

alizadeh.elham2@gmail.com

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

"No more information"

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

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

There are no plans to publish documentation or data
files.

When the data will become available and for how long

There are no plans to publish documentation or data
files.

To whom data/document is available

There are no plans to publish documentation or data
files.

Under which criteria data/document could be used

There are no plans to publish documentation or data
files.

From where data/document is obtainable

There are no plans to publish documentation or data
files.

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

There are no plans to publish documentation or data
files.

Comments