Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Mindfulness-Based Counseling on Labor Self-efficacy and Delivery satisfaction in primiparous Women

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based counseling on labor self-efficacy and delivery satisfaction in primiparous women

Design
Clinical trial with control group, with parallel, randomized groups, on 80 individuals. 4 blocks are used for randomization.

Settings and conduct
First, the city of Mashhad is divided into homogeneous areas. From all health centers in these areas, a center is selected by simple random sampling, the number of samples in each center is selected according to the population covered. All eligible persons must read and sign the Conscious satisfaction. All samples complete the questionnaire before assigning it to the groups. The meeting place is the counseling room of the health centers. The number of participants in each counseling session will be 5 to 10. The questionnaire will be completed again after the counseling sessions and also after the delivery. In the event of a corona virus prevalence, a number of intensive and minimally invasive sessions will be held. It will also be necessary to observe social distance and use masks and gloves in meetings.

Participants/Inclusion and exclusion criteria
Tendency to participate in the project, resident of Mashhad, first-born women, ages 35-18, literacy, no cesarean delivery indications, gestational age 30-28 weeks, low-risk pregnancies, no history of mental illness and no pregnancy Attend yoga classes and mind management in the last 6 months

Intervention groups
In the intervention group, in addition to receiving routine pregnancy care, women also participate in group sessions of 5 to 10 people on mindfulness counseling. In the control group, women receive only the usual prenatal care.

Main outcome variables
labor self-efficacy and delivery satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200512047412N1**
Registration date: **2020-05-25, 1399/03/05**
Registration timing: **prospective**

Last update: **2020-05-25, 1399/03/05**
Update count: **0**

Registration date
2020-05-25, 1399/03/05

Registrant information

Name
Nazanin Teimouri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3239 5054

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-19, 1399/03/30

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effectiveness of Mindfulness-Based Counseling on Labor Self-efficacy and Delivery satisfaction in primiparous Women

Public title
The effect of mindfulness counseling on self-efficacy and Delivery satisfaction

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian and Persian language Resident of Mashhad Literacy for reading and writing The desire to participate in the project Age 18 to 35 years Be her first pregnancy Gestational age 28 to 30 weeks Having a low-risk pregnancy (such as the absence of a known chronic condition such as heart disease, lung disease, high blood pressure, a history of miscarriage, and infertility)

Exclusion criteria:
History of mental illness History of psychiatric use in the past year Having disabilities and mental retardation Proven fetal abnormalities Participate in yoga classes and mind management in the last 6 months

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by blocking in order to balance the number of samples allocated to each of the studied groups. In this study, we use blocks with 4 equal numbers. The randomization unit is individual. Accidental blocking sequence websites have been used for randomization. The random sequence of blocking is assigned to a specific person outside the research team and each mother is assigned to one of the two intervention or control groups according to the time of entry and random sequence.

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 Shahroud University of Medical Sciences

Street address
Shahroud, 7th of Tir Square, Shahroud University of Medical Sciences and Health Services

City
Shahroud

Province
Semnan

Postal code
۳۶۱۴۷-۷۳۹۴۷

Approval date
2020-05-09, 1399/02/20

Ethics committee reference number
IR.SHMU.REC.1399.044

Health conditions studied

1

Description of health condition studied
delivery satisfaction

ICD-10 code

ICD-10 code description

2

Description of health condition studied
childbirth self-efficacy

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Mindfulness-based counseling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary consequence of this study is self-efficacy. Self-efficacy is defined as a person's belief in his or her ability to perform a Specific behavior.

Timepoint
The consequence of self-efficacy is measured before and after the intervention and also after delivery.

Method of measurement
The score a person receives from Louis's self-efficacy questionnaire is her labor self-efficacy score.

2

Description
Another primary consequence is Delivery satisfaction. Satisfaction means the patient's perception of the quality of medical care and the relationship between the patient and health care providers - a measure that is measured by the level of compliance with the person's expectations.
Timepoint
Consequences of maternity satisfaction is measured only once, after delivery.
Method of measurement
The score that a person receives from the McKay Maternity Satisfaction Questionnaire is her score of delivery satisfaction.

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
24 to 72 hours after delivery
Method of measurement
Hospital file

2

Description
Newborn Apgar score. Apgar score is a test that is performed on Newborns immediately after birth. In this test, skin color, heart rate, irritability, muscle consistency, and respiration are examined to determine the need for further medical care or emergency care. This test is done in the first and fifth minutes after birth.
Timepoint
After delivery
Method of measurement
Hospital file

3

Description
Success in breastfeeding immediately after delivery
Timepoint
24 to 72 hours after delivery
Method of measurement
Hospital file

4

Description
Participate in childbirth preparation classes
Timepoint
After delivery
Method of measurement
Hospital file

5

Description
Have a doula during labor
Timepoint
After delivery
Method of measurement
Hospital file

Intervention groups

1

Description
Intervention group: Intervention group: Pregnant women receive 8 group counseling sessions based on mindfulness counseling for 8 consecutive weeks. The number of people in the groups is 5 to 10, and the duration of each session will be about two hours. Each session has an educational purpose, and during the session, mindfulness exercises are performed. Homework is also recommended for women to practice mindfulness in everyday life.
Category
Behavior

2

Description
Control group: There is no additional intervention for this group of pregnant women. After 8 weeks, the questionnaire is completed again by the women.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive urban health service centers
Full name of responsible person
Nazanin Teimouri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person
Dr. Hassan Emamian

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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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Nazanin Teimouri

Position
University student

Latest degree
Bachelor

Other areas of specialty/work
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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