

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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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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	delivery satisfaction
ICD-10 code	
ICD-10 code description	
<u>2</u>	
Description of health condition studied	childbirth self-efficacy
ICD-10 code	
ICD-10 code description	
<u>3</u>	
Description of health condition studied	Mindfulness-based counseling
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
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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Person responsible for updating data

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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