

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Study of the effect of consultation based on the Pregnant mothers mind consciousness on Anxiety and Self-Efficacy In compliance with childbirth in Pregnant Women

#### Protocol summary

##### Study aim

determination of the effect of consultation Based on Self-Mindfulness on Anxiety and Self-Efficacy in Coping with Child Birth in Pregnant Women

##### Design

This Clinical practice has two groups: control group and, intervention group that participants are divided by using random numbers table in two groups of 36.

##### Settings and conduct

The selected Abyic County Centers, which include 5 comprehensive health services centers.

##### Participants/Inclusion and exclusion criteria

Exclusion :Iranian-Fluent in Persian-first pregnancy-planned pregnancy gestational age of 28-34 weeks-single pregnancy-in the absence of known disease or psychological problems Inclusion criteria:Non-participation in 2 Full Sessions of Counseling for Known MedicalConditions-Psychosocial Problems-Abortion History Intrauterine Death-Maternity Company in Childbirth Classes Occurrence of Preterm Delivery-Participants in Yoga classes, Relaxation

##### Intervention groups

In the intervention group, pregnant women with entry criteria are referred to the selected centers in Abik, who will receive weekly counseling during 5 sessions (90 minutes)

##### Main outcome variables

Anxiety- Self-efficacy in childbirth adaptation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150119020719N9**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **retrospective**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

##### Registration date

2018-05-29, 1397/03/08

##### Registrant information

###### Name

Sara Esmaelzadeh Saeieh

###### Name of organization / entity

Alborz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3433 6007

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-19, 1396/11/30

##### Expected recruitment end date

2018-05-18, 1397/02/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effect of consultation based on the Pregnant mothers mind consciousness on Anxiety and Self-Efficacy In compliance with childbirth in Pregnant Women

##### Public title

The effect of counseling on Anxiety and Self-Efficacy in Coping with Child Birth in Pregnant Women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Iranian Fluent in Persian first pregnancy planned pregnancy gestational age of 28-34 weeks single pregnancy in the absence of known disease or psychological problems

**Exclusion criteria:**

Non-participation in 2 Full Sessions of Counseling for Known Medical Conditions Psychosocial Problems Abortion History Intrauterine Death Maternity Company in Childbirth Classes Occurrence of Preterm Delivery Participants in Yoga classes, Relaxation

**Age**

No age limit

**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**

Use the random numbers table

**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 Alborz University of Medical Sciences

**Street address**

Vice-Chancellor for Research and Technology, Alborz University of Medical Sciences, above Taleghani Square, Taleghani Square, Karaj, Alborz, Iran

**City**

karaj

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2017-12-22, 1396/10/01

**Ethics committee reference number****Health conditions studied****1****Description of health condition studied**

anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**Primary outcomes****1****Description**

consultation Based on self- mindfulness

**Timepoint**

Before the intervention, After the intervention, two week after the intervention

**Method of measurement**

Freiburg Mindfulness Questionnaire

**2****Description**

Anxiety

**Timepoint**

Before the intervention, After the intervention, two week after the intervention

**Method of measurement**

Pregnancy Related Anxiety Questionnaire

**3****Description**

self-efficacy in coping with child birth

**Timepoint**

Before the intervention, After the intervention, two week after the intervention

**Method of measurement**

self-efficacy in coping with child birth questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Consultation on reducing the amount of stress based on mindfulness. Holding 6 training sessions of 60 minutes. The sessions are as follows: Session 1: Research objectives, Mindfulness definition, Self-efficacy definition, Anxiety definition. Session 2: An explanation of the process of delivery, Maternal pain, ways to reduce labor pain, and review the techniques of mindfulness, consciousness in sitting, relaxed sleep, third

session: Expression of mothers' experiences, strategies for reducing their anxiety, reviewing techniques, conscious breathing in sitting position, relaxing tone And relaxation, fourth session: teaching relaxation and explaining the activity of the home Fifth: Examination of homework, training on respiratory control training and respiratory meditation. Session Six: Review assignments, review previous sessions

**Category**

Behavior

**2****Description**

Control group receives during pregnancy routine care included pregnancy examination, fetal heart rate and all of recommended program in ministry of health and medical education guideline (after the end of consulting session in interventional group to observe ethics research booklet, containing advice, will be provided to the control group).

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Abyek Health Center

**Full name of responsible person**

Masomeh Zarenejad

**Street address**

Abyek District Health Center, Abbasi Municipality, Foundation Taleghani Street , Abyk , Qazvin

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research Assistant Alborz University of Medical Sciences

**Full name of responsible person**

Mohammad Noori Sepehr

**Street address**

Azmyh Square - Research Assistant Alborz University of Medical Sciences

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**Grant name**

Alorz University of Medical Sciences-vice President of Research

**Grant code / Reference number**

خالی

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

Yes

**Title of funding source**

Research Assistant Alborz 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**

Research Assistant Alborz University of Medical Sciences

**Full name of responsible person**

Sara Esmaelzadeh Saeieh

**Position**

faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery, first Golestan, Alborz

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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Ph.D.

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Alborz University of medical sciences

**Full name of responsible person**

Sara Esmaelzadeh Saeieh

**Position**

Faculty member

**Latest degree**

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**Email**

s-esmaelzadeh@razi.tums.ac.ir

## **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 participants data can be shared after being unidentified

**When the data will become available and for how long**

Start the access period after publishing the results

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

For use in studies

**From where data/document is obtainable**

Masoumeh Zare Nejad m13  
zare64@gmail.com-09128815318

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

The application will be sent to the project implementer by email and within 24 hours will receive the necessary item

**Comments**