

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

s-esmaelzadeh@razi.tums.ac.ir

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

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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

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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

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Alborz University of medical sciences

Full name of responsible person

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Position

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Person responsible for updating data

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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 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