

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of empowerment approach counseling on pregnancy anxiety and child birth self efficacy: a Randomized Controlled Clinical Trial

Protocol summary

Study aim

The Effect of Consultation with Empowerment Approach on Pregnancy Anxiety and Self-Efficacy Childbirth

Design

A randomized controlled clinical trial study was performed on 70 women aged 32-28 weeks old who were referred to Tabriz health centers. Contributors through random blocking using RAS software with blocks 4 and 6 will be assigned to the counseling and control groups with a 1: 1 ratio

Settings and conduct

Sampling from 16 selected health centers will be done randomly from among 80 centers of Tabriz. Then, the sampling will be made available from the selected centers. After obtaining written consent, pre-test questionnaires (demographic, Kameda empowerment, Child Birth Self Efficacy: CBSE and Pregnancy Anxiety Pregnancy Anxiety Questionnaire) will be completed by interviewing pregnant women. After 4-8 weeks after intervention, post-test questionnaires (Kameda empowerment, Child Birth Self Efficacy: CBSE and Pregnancy Related Anxiety Questionnaire) will be completed.

Participants/Inclusion and exclusion criteria

Single-swallow pregnancy; Gestational age 28 to 32 weeks; Age of 35-18 years; First pregnancy; Risk of no pregnancy; Average score of less than 62 in the self-efficacy tool ; Exit criteria: history of cesarean delivery; history of mental illness or current disease; history of participation in labor preparation class; early delivery

Intervention groups

The intervention group, four consultation sessions will be provided once a week for 90 to 120 minutes. The control group will receive only regular pregnancy care.

Main outcome variables

The main outcomes of this study were comparison of the mean of pregnancy anxiety and self-efficacy of labor in two groups of intervention (counseling) and control, before and 4-8 weeks after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N5**

Registration date: **2018-11-12, 1397/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-12, 1397/08/21**

Update count: **0**

Registration date

2018-11-12, 1397/08/21

Registrant information

Name

عصمت مهرابی

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of empowerment approach counseling on pregnancy anxiety and child birth self efficacy: a Randomized Controlled Clinical Trial

Public title

Effect of empowerment approach counseling on pregnancy anxiety and child birth self efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Single-swallow pregnancy Gestational age 28 to 32 weeks Age of 35-18 years Primiparus Risk of no pregnancy (no baseline cardiac, pulmonary, thyroid, blood pressure, diabetes and thrombosis, according to a pregnant woman.) Not having trouble communicating (distance problem, verbal problem, etc. Average score of less than 62 in the self-efficacy tool

Exclusion criteria:

A history of previous cesarean section A history of mental illness or current infection as reported by the patient Participation in Maternity Preparation Classes Recent maladaptive events that lead to mental and emotional discomfort Premature labor

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to the control and intervention groups (consultants) using the RAS software by random blocking with the size of blocks 4 and 6 and with a 1: 1 assignment ratio. To hide the allocation, after filling in the questionnaires and having the entry criteria in the order that they are sampled, the type of intervention will be written on a sheet of paper and placed inside the matte and back packed envelopes numbered (Allocation Concealment). The envelopes will be retrieved by the person not involved in the sampling and analysis of the data

Blinding (investigator's opinion)

Triple blinded

Blinding description

To hide the allocation, after After obtaining informed consent letter, filling in the questionnaires will be completed by having the entry criteria. This is a triple blind study. In the order, the type of study group (intervention or control) will be written on a sheet of

paper and placed inside the matte and back packed envelopes numbered (Allocation Concealment). The envelopes will be retrieved by the person not involved in the sampling and analysis of the data. Data analysis will be performed by who not involved in the sampling.

Placebo

Not used

Assignment

Parallel

Other design features

A randomized controlled clinical trial study was performed on 70 unplanned pregnant women referring to Tabriz health centers. Contributors through random blocking using RAS software with blocks 4 and 6 will be assigned to the counseling and control groups with a 1: 1 ratio.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

South Shariati Street; Faculty of Nursing and Midwifery of Tabriz

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5138947977

Approval date

2018-09-25, 1397/07/03

Ethics committee reference number

IR.TBZMED.REC. 1397.539

Health conditions studied**1****Description of health condition studied**

Pregnancy anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

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

Child Birth Self Efficacy

Timepoint

Before intervention ,48-24 hours after delivery and 4-8

weeks after invention
Method of measurement
Child Birth Self Efficacy Questionnaire

2

Description
Pregnancy anxiety
Timepoint
Before intervention and 4 to 8 weeks after invention
Method of measurement
Pregnancy Related Anxiety Questionnaire

3

Description
Empowerment Pregnant Women
Timepoint
Before intervention and 4 to 8 weeks after intervention
Method of measurement
KAMEDA Questionnaire

Secondary outcomes

1

Description
Empowerment
Timepoint
Before intervention and 4-8 weeks after intervention
Method of measurement
KAMEDA Questionnaire

Intervention groups

1

Description
Control group: Control group will only receive routine pregnancy care
Category
N/A

2

Description
In the intervention group, counseling during 4 sessions will be 120-90 minutes in 4 consecutive weeks
Category
Behavior

Recruitment centers

1

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Sponsors / Funding sources

Sponsor**Name of organization / entity**

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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

Tabriz 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**

Tabriz University of Medical Sciences

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Masoumeh Adeli Gargari

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Master Consultation in Miwifery

Latest degree

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Ph.Din Reproductive Health

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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

There is no further 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
No - There is not a plan to make this available
Clinical Study Report

No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available