Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of integration of psycho-educational intervention into childbirth preparation classes by midwives on the level of fear, stress, anxiety, self-efficacy of mothers

Protocol summary

Study aim

Determining the effect of integrating psycho-educational intervention into childbirth preparation classes by midwives on the level of fear, stress, pregnancy anxiety and self-efficacy of mothers.

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 110 mothers.

Settings and conduct

Two comprehensive health centers and West and East Ahvaz Health Bases have childbirth preparation classes under the supervision of Ahvaz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria Iranian nationality -Farsi language Gestation age 20-24 weeks Single pregnancy - At least reading and writing literacy - Certificate of introduction to the class from the caregiver (midwife, doctor, gynecologist) - Consent to participate in the research Exit criteria Failure to perform prenatal care - Prohibition to participate in the class in the opinion of a gynecologist or a caring midwife - Presence of obvious fetal abnormalities - Substance abuse and addiction to narcotics and psychotropic drugs and stimulants and drinking alcoholic beverages - Suffering from mental illnesses or facing unfortunate and stressful events within 6 months before the start of the study

Intervention groups

In the control group, childbirth preparation classes with the current content of the Ministry of Health are held from 20 to 37 weeks. In the intervention group, childbirth preparation classes with the content of psychological-educational intervention integration are conducted in all sessions by two trained midwives.

Main outcome variables

Fear of childbirth, stress in pregnancy, pregnancy anxiety, type of childbirth, satisfaction with childbirth, first and fifth minute Apgar of the baby, childbirth self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041963N4**
Registration date: **2024-03-12, 1402/12/22**
Registration timing: **prospective**

Last update: **2024-03-12, 1402/12/22**
Update count: **0**

Registration date

2024-03-12, 1402/12/22

Registrant information

Name

Atefeh Ebrahimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3420 0651

Email address

ebrahimiyan127@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-18, 1403/01/30

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of integration of psycho-educational intervention into childbirth preparation classes by midwives on the level of fear, stress, anxiety, self-efficacy of mothers

Public title

The effect of integration of psycho-educational intervention into childbirth preparation classes by midwives on the level of fear, stress, anxiety, self-efficacy of mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Persian language Gestation age 20-24 weeks singleton pregnancy Literacy for reading and writing Certificate of introduction to the class from the caregiver (midwife, doctor, gynecologist) Consent to participate in research

Exclusion criteria:

Lack of prenatal care Prohibition to participate in the class according to the attending gynecologist or midwife The presence of obvious fetal abnormalities Substance abuse and addiction to drugs and psychotropic drugs and stimulants and drinking alcoholic beverages Suffering from mental illnesses or facing unfortunate and stressful events within 6 months before the start of the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units are randomly divided into one of two groups of childbirth preparation classes with current content and childbirth preparation classes with the integration of psycho-educational intervention by midwives using a computerized random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, participants could not be blinded. However, the research assistants who will perform the data collection and data analysis will be unaware of the group allocation and also the participants of this study will be blinded to the study hypotheses and will not be aware of their group allocation to the intervention and control group. will be informed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address

Golestan St., Jundishapur University of Medical Sciences, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2024-02-24, 1402/12/05

Ethics committee reference number

IR.AJUMS.REC.1402.673

Health conditions studied

1

Description of health condition studied

Integration of psycho-educational intervention into childbirth preparation classes by midwives

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of childbirth

Timepoint

Version A will be completed before delivery and in the last session of childbirth preparation classes, and version B will be completed two weeks after delivery.

Method of measurement

Vijma fear of childbirth questionnaire version A and B

2

Description

Type of delivery

Timepoint

After studying

Method of measurement

check list

3

Description
Stress from childbirth
Timepoint
After studying
Method of measurement
Pregnancy stress and worry questionnaire

4

Description
Anxiety about childbirth
Timepoint
After studying
Method of measurement
Spielberger overt anxiety questionnaire

5

Description
Mothers' satisfaction with childbirth
Timepoint
After studying
Method of measurement
MacKey childbirth satisfaction questionnaire

6

Description
Childbirth self-efficacy
Timepoint
After studying
Method of measurement
Childbirth self-efficacy questionnaire

7

Description
Apgar of the baby in the first and fifth minutes
Timepoint
After studying
Method of measurement
Baby checklist

Secondary outcomes

1

Description
breastfeeding
Timepoint
After studying
Method of measurement
check list

Intervention groups

1

Description
Intervention group:: The content of psycho-educational intervention in all the sessions of childbirth preparation classes has been developed to provide information related to the childbirth process and reduce stress, anxiety, fear and preparation of pregnant women for childbirth. In the beginning, the psycho-educational content, which was prepared using reliable sources and new articles under the guidance and consultation of a gynecology and obstetrics specialist, 5 members of the academic staff of Ahvaz School of Nursing-Midwifery and 5 midwives working in teaching in Birth preparation classes will be approved. Also, corrections were made according to the opinion of these professors and at the end the final content is used in the research. After the approval, the content of the designed intervention will be printed and a video will be made available. Before the start of the research, two midwives who organize childbirth preparation classes in the intervention group in the centers of East and West Ahvaz will be taught the content of the intervention by the researchers. The content of this intervention was in 8 sessions of 90-minute childbirth preparation classes for the intervention group by two trained midwives in the centers of West and East Ahvaz who work in these centers and the experience of holding childbirth preparation classes in health centers and hospitals. will be implemented.
Category
N/A

2

Description
Control group: In the control group, childbirth preparation classes with the current content of the Ministry of Health are held from 20 to 37 weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Two comprehensive health centers and West and East Ahvaz Health Bases have childbirth preparation
Full name of responsible person
Atefeh Ebrahimian
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Golestan St, Jundi Shapur Ahvaz University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
70
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
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Abbaspoor
Position
Associate Professor
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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