

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

A comparative assessment of midwife-led counseling and "music and evidence based booklet package" on birth fear and its outcomes in pregnant women referred to the comprehensive health care centers

Protocol summary

Summary

The three-group, parallel randomized control trial study, which aimed to evaluate the effectiveness of combining music and midwife-led counseling on birth fear and its consequences. The study population will comprise pregnant women. A sample of 186 pregnant women has been calculated. Inclusion criteria with block randomization placed in one of two intervention and control groups. The main criteria are nulliparous women with 29-14 weeks gestation and the main score of birth fear would be less than 66 on WijMA-A questionnaire, miscarriage or fetal death. The two intervention groups based midwife-led counseling and music. 4 weekly sessions of group counseling and each session is 60 minutes. The music group at the same time will listening to self-selected music part for 15-30 minutes at home and would mark their checklist. Before and after the intervention and 2 weeks after the last sessions, the outcomes of birth fear will be assessed, comprise of decision-making conflict, anxiety, depression, and self-efficacy are likely to be measured by questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030627557N3**
Registration date: **2017-05-28, 1396/03/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-28, 1396/03/07

Registrant information

Name

Mahnaz Akbari Kamrani

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 26 3433 6007

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dr.akbarikamrani@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences

Expected recruitment start date

2017-04-19, 1396/01/30

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative assessment of midwife-led counseling and "music and evidence based booklet package" on birth fear and its outcomes in pregnant women referred to the comprehensive health care centers

Public title

A comparative assessment of midwife-led counseling and "music and evidence based booklet package" on birth fear in pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: primiparous women 29-12 weeks attend

to get free prenatal care; women must have the ability to communicate; ability to read and write, be 18 years of age or older. Exclusion criteria: having acute and chronic neuropsychiatric disorders; neuropsychiatric drug use; proven fetal abnormalities; impaired hearing; not wanting to continue collaborating in the study; less fear score of 66 with WIJMA-A questionnaire; fetal death.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **186**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Sciences

Street address

Department of Midwifery, Alborz University of Medical Sciences, Eshteraki St., Baghestan Blv

City

Karaj

Postal code

56131452

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

Abzums.Rec.1395.149

Health conditions studied

1

Description of health condition studied

Birth fear

ICD-10 code

F40.8

ICD-10 code description

Other phobic anxiety disorders

Primary outcomes

1

Description

Birth fear

Timepoint

Before and after intervention, 2 weeks after the end of intervention

Method of measurement

WDEQ-version A questionnaire

Secondary outcomes

1

Description

Self-efficacy

Timepoint

Before and after of intervention, 2 weeks after end of intervention

Method of measurement

Child Birth Self-efficacy Inventory questionnaire

2

Description

Decision conflict

Timepoint

Before and after of intervention, 2 weeks after end of intervention

Method of measurement

Decision Conflict Scale

3

Description

Mood of delivery

Timepoint

Before and after of intervention, 2 weeks after end of intervention

Method of measurement

Obstetric's information Questionnaire

4

Description

Anxiety

Timepoint

Before and after of intervention, 2 weeks after end of intervention

Method of measurement

STAI questionnaire

5

Description

Depression

Timepoint

Before and after of intervention, 2 weeks after end of

intervention

Method of measurement

Edinburgh Postnatal Depression Scale

Intervention groups

1

Description

First group: Midwife-led counseling group, Receive 4 sessions counseling intervention in 26-33 weeks gestation.

Category

Behavior

2

Description

Second group: Music listening group will listen a self selected classical music part for 15-30 minutes daily in 26-33 weeks gestation. An evidence base booklet has been prepared for this group about birth fearing.

Category

Behavior

3

Description

Third group: Control group will receive routine prenatal care, In 26-33 weeks gestation. They will receive an evidence based booklet about birth fearing.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Comprehensive Health Care Center

Full name of responsible person

Yalda Shakouri Masouleh

Street address

Alghadir Building, Bahman St., Rahahan Blv.

City

Hashtgerd New city

2

Recruitment center

Name of recruitment center

Kalimollah Maadandar Comprehensive Health Care Center

Full name of responsible person

Yalda Shakouri Masouleh

Street address

Tejarat Building, Emamkhomaini St., Emamkhomaini Blv.

City

Hashtgerd

3

Recruitment center

Name of recruitment center

Nejad Fallah comprehensive health care center

Full name of responsible person

Yalda Shakouri Masouleh

Street address

Beside Jame Mosque, Shahrdari St.

City

Hashtgerd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

Street address

Research and Technology Office, Alborz University of Medical Sciences, Yasamin St., Poneh St., Golshahr BLv.

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Yalda Shakouri Masouleh

Position

Student

Other areas of specialty/work

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Postal code
Phone

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty