

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of group education on the anxiety of pregnant women at risk of preterm delivery

Protocol summary

Study aim

determine the effect of group education on the anxiety of pregnant women at risk of preterm delivery

Design

This study is a clinical trial with two groups of intervention and control. 72 pregnant women at risk of preterm delivery with gestational age of 24-28 weeks entered the study at Shaheed Akbar Abadi Hospital in Tehran. block randomization method with blocks of 4, they will be divided in to two groups: control and intervention.

Settings and conduct

Participants ,who have conditions for entry the study, will be divided randomly into two groups.The intervention group (36 persons), In addition to routine pregnancy care, six 60-minute sessions of Group education Will receive during 6 weeks (once a week). The control group (36 persons) only received routine pregnancy care. The Pregnancy Related Anxiety Questionnaire Vanden Berg is completed three times before, the end of the 6th session and one month after the end of the session in the intervention group and before, the 6th and 10th week after the study in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian; Resident in Tehran; With lowest literacy of reading and writing; Willingness to participate in the research; Single and live fetus; Gestational age between 24 and 28 weeks; Scores 10 or more of 10 from Holbrook risk-scoring for preterm labour questionnaire; Having anxiety score (17-119) on the Vanden Berg anxiety scale. Exclusion criteria: Having drug addiction; History of mental illness

Intervention groups

Intervention groups: receive routine care during pregnancy and 6 sessions of Group education. Control groups: receive routine care during pregnancy

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041965N1**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

Registration date

2019-02-06, 1397/11/17

Registrant information

Name

Somayeh Bazrafshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4417 1527

Email address

bazrafshan.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group education on the anxiety of pregnant women at risk of preterm delivery

Public title

The effect of group education on the anxiety of pregnant women at risk of preterm delivery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian Resident in Tehran With lowest literacy of reading and writing Willingness to participate in the research Single and live fetus Gestational age between 24 and 28 weeks Scores 10 or more of 10 from Holbrook risk-scoring for preterm labour questionnaire Having anxiety score (17-119) on the Vanden Berg anxiety scale

Exclusion criteria:

Having drug addiction History of mental illness

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

Random assignment by blocking method and using all possible combinations of AABB blocks. For each combination, a code will be allocated and 18 codes will be randomly selected. Then, with regard to the blocks corresponding to each code and the existing combinations, we will add people to the study.

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.522

Health conditions studied

1

Description of health condition studied

Preterm labour

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

Primary outcomes

1

Description

anxiety

Timepoint

before, the end of the 6th session and one month after the end of the session in the intervention group and before the 6th and 10th week after the study in the control group

Method of measurement

Pregnancy Related Anxiety Questionnaire Vanden Berg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, McNamara anxiety management is used in six one-hour sessions during six weeks, when pregnant mothers at risk of preterm delivery receive educational intervention in groups of 4 to 6 mothers. In each session, new topics are presented after reviewing previous ones, and issues discussed are summed up at the end of the session. The sessions are as follows: Session 1: welcome, an overview of the rules and regulations of group educating sessions, meet the members together, research objectives, preterm delivery. Session 2: presenting definitions of anxiety, Introducing general effects of anxiety on various body systems, and examining physical and behavioral effects of anxiety, Introduction to the importance of learning anxiety management skills. Session 3: Subjective and rational strategies for dealing with anxiety. Session 4: physical ways of coping with anxiety. Session 5: communication skills training. Session 6: building self-

confidence and self-esteem, review previous sessions. anxiety levels is measured using pretest and post test, and anxiety levels in two groups are compared through post test and follow-up test.

Category

N/A

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 educational sessions in intervention group to observe ethics research booklet, containing advice, will be provided to the control group).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Akbar Abadi hospital

Full name of responsible person

Somayeh Bazrafshan

Street address

Molavi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Somayeh Bazrafshan

Position

Senior Student of Consultation in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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)

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

Not applicable

Title and more details about the data/document

The data after ending the thesis is worthy of publishing

When the data will become available and for how long

Six month after ending the thesis

To whom data/document is available

Researchers, IRAN University of Medical Sciences,
University and Hospital Researchers

Under which criteria data/document could be used

Data after analysis, is available to others through
publication in scientific journals

From where data/document is obtainable

Somayeh bazrafshan, Email:
Bazrafshansomayeh@gmail.com

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

Usually, information will be available through the
publication of the paper. But if the person asks for more
and more information, can submit application by email .

Comments