

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluating the effectiveness of education based on empowerment for nulliparous women on their empowerment and anxiety

Protocol summary

Summary

Objectives: The aim of this study is to investigate the effect of education based on empowerment for nulliparous women on their empowerment and anxiety.

Method: This is a randomized clinical trial. In this study, 70 nulliparous women who are in gestational ages of 20 - 24 weeks should be randomly placed in intervention and control groups with 35 people in each one. Inclusion criteria: having a low-risk pregnancy; the lack of use particular drug; no history of mental health problems or hospitalization related to mental health problems; having ages of 18 to 35; singleton pregnancy. Exclusion criteria: people who are treated for anxiety disorders; mothers who are involved by complication of pregnancy such as hypertension; toxemia of pregnancy; gestational diabetes; intrauterine fetal death and premature labor; during the study period, the mothers who do not attend at least two sessions of training sessions. Interventions: Pregnant women education based on empowerment which is an organized program will be done on 4 groups by 9 persons in each one. They will be attended in 4 training sessions during 4 weeks. Each session will be held in 90 minutes. In control group, prenatal care and education will be done individually. The main outcome variables: Pregnant women empowerment questionair and Spielberger State-Trait Anxiety Inventory will be completed before the intervention, immediately and 8 weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506042248N16**

Registration date: **2015-08-20, 1394/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-20, 1394/05/29

Registrant information

Name

Fereshteh Jahdi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of education based on empowerment for nulliparous women on their empowerment and anxiety

Public title

Effectiveness of the education based on empowerment for pregnant women on their empowerment and anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Iranian pregnant women; The first pregnancy; A low-risk pregnancy; A mild to moderate anxiety according to Spieberger Anxiety Scale; Gestational age 20 to 24 weeks; The lack of use particular drug; No history of mental health problems or hospitalization due to mental health problems; Age between 18 to 35 years; With literacy; Singleton pregnancy; No accidents in the last 3 months for the individual and first degree relatives. Exclusion criteria: The presence of known physical and mental illness such as diabetes; heart disease and psychosis including schizophrenia and paranoia that requires special medication and care; People who are treated for anxiety disorders; During the study; mothers who are involved by complication of pregnancy such as hypertension, toxemia of pregnancy; gestational diabetes; intrauterine fetal death; premature labor; Mothers who don't desire to continue; Women who do not attend at least two sessions of training sessions.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, for sampling will be used the closed envelope.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Postal code

Approval date

2015-05-26, 1394/03/05

Ethics committee reference number

IR.IUMS.REC.1394.26091

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Pregnant women empowerment

Timepoint

Before the intervention, immediately and 8 weeks after the intervention.

Method of measurement

Pregnant women empowerment questionair

Secondary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, immediately and 8 weeks after the intervention.

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI)

Intervention groups

1

Description

Intervention group: After completing initial demographic questionnaires, pregnant women empowerment questionnaires, Spielberger State-Trait Anxiety Inventory and having inclusion criteria, samples will be trained by instructor. Pregnant women education based on empowerment which is an organized program will be done on 4 groups by 9 persons in each one. They will be attended in 4 training sessions during 4 weeks. Each session will be held in 90 minutes. Pregnant women empowerment questionnaires and Spielberger State-Trait Anxiety Inventory again will be completed immediately and 8 weeks after the intervention.

Category

Prevention

2

Description

Control group: There is not any intervention in control group, prenatal care and education to be done individually.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Training - Medical center Akbar Abadi

Full name of responsible person

Fereshteh Jahdi

Street address

Ferdose garden station, Molavi street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr.Seyed Ali Javad Moosavi

Street address

Hemmat Highway

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran 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

School Nursing and Midwifery

Full name of responsible person

Zahra Koohsarian

Position

Master of midwifery

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty