

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effects of spouse participation in childbirth preparation classes on fear of childbirth and Select the type of delivery in Nulliparous women

Protocol summary

Summary

1-Objectives: this study aims to determine the effect of the presence of spouse in preparation class of delivery on fear of parturition and choosing type of childbirth in the women nulliparous 2- Design: This is a controlled randomized trial will be conducted in 152 pregnant women referred to delivery preparation class in Qazvin 3- How to do: eligible subjects will be selected by a convenience sampling method, Harman fear of delivery questionnaire will be completed for them and women with fear will enter the research. Then they division in two intervention group and control group by the 4block method. 4- Participants including major eligibility criteria: 20-30 Weeks pregnant women with low danger pregnancy: first pregnancy: singleton pregnancy: scores 28 and more in the fear of accouchement questionnaire and men that would like to participate in research. women who suffering by chronic disease including high blood pressure, diabetes, cardiovascular disease and etc.: sterility history and pregnancy using assist reproduction method: mental disease history or using medicine. Men and women who would not like to participate in study for any reason will be removed. 5- interventions: beside usual medical care the intervention group should participate in 6 session delivery preparation class ,fill the fear of delivery questionnaire before and after intervention. 6- The main outcome variables: fear of delivery and choosing type of delivery with or without the presence of spouse will be assessed before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705011113N8**

Registration date: **2017-09-10, 1396/06/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-10, 1396/06/19

Registrant information

Name

Fatemeh Ranjkesh

Name of organization / entity

Qazvin University Of Medical Sciences, Nursing & Midwifery school

Country

Iran (Islamic Republic of)

Phone

+98 28 1335 9501

Email address

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2018-03-01, 1396/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of spouse participation in childbirth preparation classes on fear of childbirth and Select the type of delivery in Nulliparous women

Public title

The effects of spouse participation on fear of childbirth and select the type of delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Women inclusion criteria :20_30 weeks pregnant women with low danger pregnancy : First pregnancy : Singleton pregnancy : Ability to read and write: Scores 28 and more in the fear of accouchement questionnaire : Availability and follow up. Men inclusion criteria : men who would like to participate in research: Ability to read and write : Availability and follow up. Women Exclusion criteria : Women who would not like to participate for any reason :women who suffering by chronic disease including high blood pressure, diabetes, cardiovascular disease and etc :sterility history and pregnancy using assist reproduction method :Mental disease history or using medicine. Men Exclusion criteria: men who would not like to participate for any reason

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

No design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Bahonar boulevard , Qazvin University of Medical Sciences

City

Qazvin

Postal code

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.QUMS.REC.1395.303

Health conditions studied

1

Description of health condition studied

Nulliparous women

ICD-10 code

Z34.0

ICD-10 code description

Supervision of normal first pregnancy

Primary outcomes

1

Description

Fear of childbirth

Timepoint

Before and after intervention

Method of measurement

Questionnaire

2

Description

Select the type of delivery

Timepoint

Before and after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will participate in 6 session (90 minutes per each session) in accouchement preparation class and their fear of accouchement and choosing type of accouchement will be assessed before and after the intervention.

Category

Prevention

2

Description

For the control group, accouchement preparation class will be held without husband.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dehkhoda Hospital
Full name of responsible person
Fatemeh Ranjkesh
Street address
City
Qazvin

2

Recruitment center
Name of recruitment center
Soroud afarinesh Counseling Center
Full name of responsible person
Fatemeh Ranjkesh
Street address
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Peymani
Street address
Bahonar Boulevard , Qazvin University of Medical Sciences
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
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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