

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of spouses education Classes on quality of life and pregnancy outcomes in primiparous women

Protocol summary

Summary

The aim of this clinical trial, not blinded study was to determine the effect of spouse education classes on quality of life and pregnancy outcomes in primiparous women referred to Shahrekord clinic of Hajar hospital. Pregnant women were allocated randomly by computer soft ware in two control (n=27) and intervention (n=31) groups. Inclusion criteria were primiparous women; gestational age of 20 weeks, and single pregnancy and exclusion criteria were previous history of marriage of man or woman, having psychiatry disorder, and having any pregnancy complication such as preeclampsia , intrauterine fetal death and preterm labor. Educational classes for pregnant women in two intervention and control groups held according to national guideline for physiologic delivery in 8 sessions every two weeks (each session 90 minutes). In intervention group, spouse of pregnant women participated in sessions three and eight concomitant their women. Quality of life questionnaire was completed in two groups before beginning the first session and 3 weeks after the eighth session. In addition, in two groups, pregnancy outcomes such as mother's weight gain, birth weight, type of delivery, gestational age, head circumference and neonatal apgar were assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904092265N3**

Registration date: **2013-09-07, 1392/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Faranak Safdari Decheshmeh

Name of organization / entity

Shahrekord Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5648

Email address

safdari@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Shahrekord University of Medical Sciences

Expected recruitment start date

2011-10-02, 1390/07/10

Expected recruitment end date

2012-06-04, 1391/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spouses education Classes on quality of life and pregnancy outcomes in primiparous women

Public title

The effect of spouses education Classes on quality of life and pregnancy outcomes in primiparous women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Primiparous women; gestational age of 20 weeks and single pregnancy. Exclusion criteria: Previous history of marriage of man or woman; having

psychiatry disorder, and having any pregnancy complication such as Preeclampsia, intrauterine fetal death and preterm labor.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Vice chancellor for research and technology,
Shahrekord University of Medical Sciences

Street address

Aytollah Kashani Street, Shahrekord

City

Shahrekord

Postal code

Approval date

2011-03-13, 1389/12/22

Ethics committee reference number

89-12-5

Health conditions studied

1

Description of health condition studied

pregnancy

ICD-10 code

Z34

ICD-10 code description

Supervision of other normal pregnancy

Primary outcomes

1

Description

Quality of life

Timepoint

Before beginning the first session and 3 weeks after the eighth session

Method of measurement

Quality of life questionnaire

2

Description

Pregnancy outcomes

Timepoint

Before beginning the first session and 3 weeks after the eighth session

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Educational classes for pregnant women in control group held according to national guideline for physiologic delivery in 8 sessions every two weeks (each session 90 minutes).

Category

Treatment - Drugs

2

Description

Intervention group: In intervention group, spouse of pregnant women participated in sessions three and eight concomitant their women.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Hajar hospital

Full name of responsible person

Faranak Safdari Decheshmeh

Street address

Hajar hospital, Parastar Street, Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology,
Shahrekord University of Medical Sciences

Full name of responsible person

Dr Mahmood Mobasheri

Street address

Aytollah Kashani Street, Shahrekord University of
Medical Sciences, Shahrekord

City

Shahrekord

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 and technology, Shahrekord
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

Shahrekord University of Medical Sciences

Full name of responsible person

Faranak Safdari Decheshmeh

Position

Lecturer

Other areas of specialty/work

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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