

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effects of companionship of trained husbands beside their women during childbirth on women's anxiety level, Isfahan University of Medical sciences, Zahraye Marzieh hospital, 2014

Protocol summary

Summary

Aim: Determining the effect of presence of husbands beside their women during childbirth on mother's anxiety level. Design: Randomized, three period, not blinded, three groups Population: Pregnant women visited in obstetric clinic and willing to deliver in labour part of Zahraye Marzieh hospital Inclusion criteria: Iranian women, Age between 20-35, First and wanted pregnancy, Gestational age of 28-37 weeks, not having an active or chronic history of psychological disorders, having the physical and psychological health to participate in educational classes for both women and their husbands, single fetus and presentation of head, not having congenital disorders according to sonography, no history of smoking, opium addiction, and alcohol drinking, vaginal and non-complicated delivery with healthy infant. Main exclusion criteria: Congenital disorders of fetus, Indication of cesarean section for any reason (umbilical cord prolapse, placenta previa, Decolman of placenta, ...) , Encounter with any stressor like death of family members, special diseases or preterm labour (before 37W), Unwilling to continue of research, not participating in educational classes or presence in at least active phase of delivery, showing anxiety reactions from woman or her husband Sample size: 84 pregnant women Intervention: The effect of presence of husbands beside their women during childbirth. Time of intervention: Before, during, and after delivery Outcomes: Change of anxiety level

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120525376N1**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Atefeh Salehi

Name of organization / entity

Faculty of nursing and midwifery

Country

Iran (Islamic Republic of)

Phone

+98 31 3442 6105

Email address

atisaleh63@gmail.com

Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Isfahan university of medical sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of companionship of trained husbands beside their women during childbirth on women's anxiety level, Isfahan University of Medical sciences, Zahraye Marzieh hospital, 2014

Public title

The effect of presence of husband beside women during delivery on mother's anxiety level

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian women; Age between 20-35; First and wanted pregnancy; Gestational age of 28-37 weeks; not having an active or chronic history of psychological disorders; having the physical and psychological health to participate in educational classes for both women and their husbands; single fetus and presentation of head; not having congenital disorders according to sonography; no history of smoking; opium addiction and alcohol drinking; vaginal and non-complicated delivery with healthy infant. Exclusion criteria: Congenital disorders of fetus; Indication of cesarean section for any reason (umbilical cord prolapse, placenta previa, Decolman of placenta, ...); Encounter with any stressor like death of family members; special diseases or preterm labour (before 37W); Unwilling to continue of research; not participating in educational classes or presence in at least active phase of delivery; showing anxiety reactions from woman or her husband.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **84**

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**

Moral committee of Isfahan university of medical sciences

Street address

update Isfahan university of medical sciences, Azadi square, Hezar Jarib street, Isfahan

City

Isfahan

Postal code

8174673461

Approval date

2014-05-08, 1393/02/18

Ethics committee reference number

lr.mui.rec.1393.3.831

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**

anxiety level

Timepoint

Before, during, and after delivery

Method of measurement

state-trait anxiety inventory

Secondary outcomes**1****Description**

nothing

Timepoint

nothing

Method of measurement

nothing

Intervention groups**1****Description**

Intervention group (With husband presence): In this group pregnant women with gestational age of 28-37 weeks in two times before delivery participated in pregnancy educational classes. In this classes they learned about process of hospitalization and role of husband during delivery and the way of emotional support of their wife during delivery. In the active phase of labor husbands with presence beside their wife supported them and encouraged them to collaborate with treatment team.

Category

Prevention

2

Description

Group 2 (With Doula support): In this group one of the relatives of pregnant woman who hadn't participated in educational classes before delivery, supported her emotionally during delivery.

Category

Prevention

3

Description

Group control (Without companion): In this group none of the relatives of pregnant women presented beside them during labor. Only routine cares by midwives was done for them during labor.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Zahraye Marzieh hospital

Full name of responsible person

Atefeh Salehi

Street address

Ghods square, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research, Isfahan university of medical sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Isfahan university of medical sciences, Hezar Jarib street, Azadi square, Isfahan, Iran

City

Isfahan

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, Isfahan 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

Isfahan university of medical sciences, Faculty of nursing and midwifery

Full name of responsible person

Atefeh Salehi

Position

MS student of midwifery

Other areas of specialty/work

Street address

Faculty of nursing and midwifery, Isfahan university of medical sciences, Hezar Jarib street, Azadi square, Isfahan

City

Isfahan

Postal code

8174673461

Phone

+98 317922901

Fax

Email

atisaleh63@gmail.com; atisaleh63@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan university of medical sciences, Faculty of nursing and midwifery

Full name of responsible person

Atefeh Salehi

Position

MS student of midwifery

Other areas of specialty/work

Street address

Faculty of nursing and midwifery, Isfahan university of medical sciences, Hezar Jarib street, Azadi square, Isfahan

City

Isfahan

Postal code

8174673461

Phone

+98 31 3792 2901

Fax

Email

atisaleh63@gmail.com; atisaleh63@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan university of medical sciences, Faculty of nursing and midwifery

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Postal code

8174673461

Phone

+98 31 3792 2901

Fax**Email**

atisaleh63@gmail.com; atisaleh63@yahoo.com

Web page address

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