

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of companionship during labour, on anxiety and breastfeeding desire in primiparous mothers in Iranshahr city 2009-2010

Protocol summary

Summary

OBJECTIVE: child birth is the most emotional experience near the primiparous women, which effects on their health or illness in their whole life. Being alone in childbirth environments, leads to anxiety and complication due to such situation in labour So we decided to evaluate the effects of psychosocial support during labour, delivery and the immediate postpartum period provided by a female relative companion on state anxiety and breastfeeding desire in nuliparous women in Iran hospital in Iranshahr 2009-2010. **DESIGN:** The effects of the intervention were assessed by means of a randomised clinical trial. Emotional support by a female relative was provided to women in the intervention group, while women in the control group received routine care. **SETTING:** A main governmental hospital in Iranshahr City **PARTICIPANTS:** two hundred and ten women with a single foetus, no previous vaginal delivery, < 3 cm of cervical dilatation, and no indications for an elective caesarean section were randomly assigned to be in control group who received routine care, or being in support group. Intervention group accompanied by a relative woman, who accepted to remain by the labouring mother from the time of admission until one hour after birth. She must talk while keeping mother's hand, giving reassurance and praise them. **OUTCOME MEASURES:** mother's state anxiety score at the admission, mother's state anxiety score in 6-8 cm dilation of cervix, Breastfeeding desire, first Breastfeeding initiation time, duration of labour, mother perception to the birth, newborn's apgar score, and disturbances caused by the companions in delivery ward. **Keywords:** Labour, breastfeeding, Anxiety, companionship

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807062516N1**

Registration date: **2010-12-04, 1389/09/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-04, 1389/09/13

Registrant information

Name

Tayebeh Samieizadeh Toosi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 7331 0482

Email address

samieizadeht@zdmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2009-07-11, 1388/04/20

Expected recruitment end date

2010-06-10, 1389/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of companionship during labour, on anxiety and breastfeeding desire in primiparous mothers in Iranshahr city 2009-2010

Public title

The effect of companionship during labour, on anxiety and breastfeeding desire in primiparous mothers in Iranshahr city 2009-2010

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: mothers with single baby; term (38-42 gestational ages); primiparous; without medical and obstetrical complication; desire to enter in the study
Exclusion criteria: mothers with caesarean and complicated delivery; High risk pregnancy; premature rupture of membrane

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **210**

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

Ethics committee of Zahedan University of Medical Sciences

Street address

Khalij Fars blv., Zahedan University of Medical Sciences

City

ZAHEDAN

Postal code

9816743463

Approval date

2010-06-19, 1389/03/29

Ethics committee reference number

89942

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

state anxiety score

Timepoint

time of admission in first stage of labour at 3 cm dilation of cervix then on 6-8 dilation of cervix in first stage of labour

Method of measurement

spielbergers state-trait anxiety score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: female companion from admission to delivery time

Category

Behavior

2

Description

control group: received routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran hospital

Full name of responsible person

Tayebeh Samieizadeh Toosi

Street address

IRANSHAHR, faculty of Nursing and Midwifery

City

IRANSHAHR

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

abasalt borji

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Khalij Fars blv., Zahedan University of Medical Sciences

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Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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**

Faculty of Nursing and Midwifery

Full name of responsible person

Tayebeh Samieizadeh Toosi

Position

MS of Education in midwifery

Other areas of specialty/work**Street address**

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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