Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Street address
Khalij Fars blv., Zahedan University of Medical Sciences
City
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
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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