Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of companion’s support on fear and self-efficacy of delivery

Protocol summary

Study aim

Determining the effect of companion’s support on the fear and self-efficacy of labor

Design

A clinical trial will be conducted on 114 primiparous pregnant women who are referred with cervical dilatation of 5-4 cm. Research units are randomly allocated to three groups of midwives (intervention), relatives and friends (control 1) and unmarried (control 2).The data collection tool was a demographic questionnaire, a phobia questionnaire, a self-efficacy questionnaire for labor and a McKay standard questionnaire to measure the satisfaction of delivery.

Settings and conduct

They receive the usual midwifery care group. The intervention group is provided by the researcher as a midwife with psychosocial, physical, educational support and supportive care of the cervical dilatation of 5-4 cm until two hours after delivery. Control group 1 supports 4 to5 cm dilation of the cervix up to two hours after delivery according to the usual method of the hospital, which will be used to select a woman from a family, or family, or from friends. The control group (2) receives only routine care. Data collection tools consisted of demographic data, demographic questionnaire, maternal phobia questionnaire, labor self-efficacy questionnaire, and McKay standard questionnaire for measuring the satisfaction of delivery. Maternal self-efficacy and DFS delivery questionnaire is completed at the age of 4-5 cm (at the time of admission), dilatation of 8-10 cm DFS , in the second stage of the labor (crooning step) and self-check questionnaire half an hour later. Fear of Vijima Maternity Delivery Questionnaire (version b) and satisfaction questionnaire completed two hours after delivery.Omolbnen Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian nationalty; written informed consent; primiparous; low-risk pregnancy; cervical dilatation of 4-5 cm; age 18 to 35 years old; gestational age 38 weeks and more; no major underlying disease (diabetes, high blood pressure, epilepsy, heart disease, asthma); no initial indication of cesarean section; fetal weight of 2500-4000 grams. Exclusion criteria: tobacco use and narcotic drugs; cesarean section indication at each stage of the study; pregnancy become high risk including bleeding or fetal distress; use of analgesic methods including spinal and epidural analgesia; use of entonox and reluctance to continue to participate in the study.

Intervention groups

The intervention group is provided by the researcher as a midwife with psychosocial, physical, educational support and supportive care of the cervical dilatation of 4-5 cm until two hours after delivery. Control group (1) supports 4 to 5 cm dilation of the cervix up to two hours after delivery according to the usual method of the hospital, which will be used to select a woman from a family, or family, or from friends. The control group (2) receives only routine care

Main outcome variables

Maternal self-efficacy and DFS delivery questionnaire is completed at the stage of 4-5 cm (at the time of admission), dilatation of 8-10 cm, DFS in the second stage of the labor (crooning step) and self-check questionnaire half an hour later. wijma Maternity Wear Questionnaire (version b) and Delivery Satisfaction Questionnaire completed two hours after delivery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160625028630N2**
Registration date: **2018-02-18, 1396/11/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-18, 1396/11/29**
Update count: **0**

Registration date

2018-02-18, 1396/11/29

Registrant information

Name

Sima Saeedi aval nookabe

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 6675

Email address

saeedins931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2017-12-16, 1396/09/25

Expected recruitment end date

2018-04-17, 1397/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of companion’s support on fear and self-efficacy of delivery

Public title

The effect of companion’s support on fear and self-efficacy of delivery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality written informed consent primiparous low-risk pregnancy cervical dilatation of 5-4 cm age 18 to 35 years gestational age of 38 weeks and more no major underlying disease (diabetes, hypertension, epilepsy, heart disease, Asthma no initial indication of cesarean section, Weight 2500-4000 gr of fetus

Exclusion criteria:

tobacco use and narcotic drugs cesarean section indication at each stage of the study being pregnancy complicated including bleeding, fetal distress use of analgesic methods including spinal and epidural analgesia use of entonox reluctance to continue to participate in the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment using computer software

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Mashhad University of Medical Sciences

Street address

Ebne- Sina Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2017-11-28, 1396/09/07

Ethics committee reference number

IR.MUMS.REC.1396.255

Health conditions studied

1

Description of health condition studied

Fear of delivery and self-efficiency of delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of delivery

Timepoint

cervical dilatation of 4-5 cm, cervical dilatation of 10-8 cm, second stage of labor (the stage of crowning and before exit of fetus) and two hours after delivery

Method of measurement

Delivery Fear Scale Questionnaire and Vijima Maternity

Delivery Questionnaire

Secondary outcomes

1

Description
Self-efficacy of delivery
Timepoint
cervical dilatation of 4-5 cm, cervical dilatation of 10-8 cm, and half an hour after delivery (self-efficacy of the stage of crowning and before exit of fetus will be asked)
Method of measurement
Self-efficacy questionnaire

2

Description
Delivery satisfaction
Timepoint
Two hours after delivery
Method of measurement
McKay Maternity Satisfaction Questionnaire

Intervention groups

1

Description
The intervention group, in addition to the routine maternity care in delivery ward, will provided physical, mental, educational and supportive care support by companion’s midwife from cervical dilatation of 4-5 cm until 2 hours after delivery.
Category
Other

2

Description
The control group (1), in addition to the routine maternity care in delivery ward, will receive support of a woman, who was chose by herself, from family/ relatives or friends from cervical dilatation of 4-5 cm until 2 hours after delivery.
Category
Other

3

Description
The control group (2) only receives routine maternity care in delivery ward.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Maternity Hospital of Umm Al-Benin
Full name of responsible person
Sima Saeedi Aval Noughabi
Street address
Zarrineh Crossroad - Ayatollah Behjat Ave. - Ayatollah Bahjat Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
96991901
Phone
+98 51 3223 1061
Fax
+98 51 3223 1444
Email
OAH.IT@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Saeed Islami
Street address
Ebne- Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3841 1538
Fax
+98 51 3843 0249
Email
moradim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Sima Saeedi Aval Noughabi

Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work

Street address
School of Nursing and Midwifery

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Fax
+98 51 3859 7313

Email
saeedins931@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Moradi (Ph.D)

Position
Assistant Professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Ibne Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Fax
+98 51 3859 7313

Email
moradim@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Sima saeedi Avall Nogabi

Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Ibne Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Fax
+98 51 3859 7313

Email
saeedins931@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available