

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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 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. 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 nationality; 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. VijiMa 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

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Name of organization / entity

Mashhad University of Medical Sciences

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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

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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

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Sponsors / Funding sources

1

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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

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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