

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of midwife's continues support in labor on the childbirth experience and self-esteem of primipara women

Protocol summary

Study aim

Determining the effect of continuous midwifery support in labor on delivery experience and self-esteem of nulliparous women

Design

A randomized controlled trial with two parallel groups, one-way blind, phase 3, on 70 pregnant women admitted to the maternity ward. Web-based calculators will be used to create allocation sequences based on 4 blocks.

Settings and conduct

After obtaining the code of ethics and obtaining permission from the Vice Chancellor for Research of Hamadan University of Medical Sciences, the objectives and method of study are explained to pregnant women with inclusion criteria. After obtaining informed written consent and assigning individuals based on the sequence of allocation to the two groups, the researcher on the mother's bedside is placed in the intervention group and the necessary support is provided up to 2 hours after delivery. Then, 6 weeks after delivery, Rosenberg Maternity Experience and Self-Esteem Questionnaires are completed by mothers. The person responsible for submitting the questionnaires to the mother and collecting them will not be aware of the type of allocation.

Participants/Inclusion and exclusion criteria

Pregnant women who are admitted to the maternity ward for normal delivery.

Intervention groups

In the intervention group, in addition to routine care, the researcher is present at the mother's bedside and will be with the mother during the whole labor and up to 2 hours after delivery and will provide the necessary support to the mother. These include emotional support, information about the labor process and advice on coping techniques, encouragement of mobility and adequate fluid intake, and support. People in the control group will receive only routine care.

Main outcome variables

Childbirth experience Mother's self esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201102049233N1**

Registration date: **2021-06-06, 1400/03/16**

Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**

Update count: **0**

Registration date

2021-06-06, 1400/03/16

Registrant information

Name

Farideh Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

f.kazemi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of midwife's continues support in labor on the childbirth experience and self-esteem of primipara women

Public title

midwife's continues support in labor

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 35-18 years No history of childbirth live fetus with cephalic presentation Single pregnancy Pregnancy 37 to 41 weeks No pregnancy complications No chronic medical problems 4 cm dilatation during hospitalization Be literate No history of infertility No accompanying midwife

Exclusion criteria:

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign mothers to the intervention and control groups, a quadruple random blocking method is used. To do this, the allocation sequence is first determined using AABB blocks before the start of the study. Then, the type of intervention is written in opaque closed envelopes based on the specified sequence and is numbered in sequence. Participants will complete a demographic and midwifery information questionnaire and receive an envelope before entering the study. People are then placed in one of the control or intervention groups based on the contents of the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Another person outside the research team is responsible for delivering the questionnaire to the participants and collecting it and will not be aware of the assigned intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

In front of Mardom's Park, Research Square

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۸۷

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.UMSHA.REC.1399.474

Health conditions studied

1

Description of health condition studied

labor stage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean score of childbirth experience and self-esteem of nulliparous women

Timepoint

6 weeks after delivery

Method of measurement

Childbirth Experience Questionnaire, Rosenberg Self-Esteem Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Continuous support includes emotional support (e.g., constant presence and reassurance and encouragement), information about the labor process and counseling on coping techniques, encouragement of mobility and adequate fluid intake, and support (such as helping a woman express her wishes to others)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital in Hamedan

Full name of responsible person

Farideh Kazemi

Street address

Pasdaran Ave

City

Hamedan

Province

Hamadan

Postal code

6517997178

Phone

+98 81 3827 7012

Email

faridehkazemi21@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. saeid bashirian

Street address

Mardom's Park, Pajouhesh Square

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۸۷

Phone

+98 81 3838 0717

Email

faridehkazemi21@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr.Farideh Kazemi

Position

instructor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

in front of Mardom's Park, Pajouhesh Square

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۸۷

Phone

+98 81 3838 0579

Email

faridehkazemi21@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farideh Kazemi

Position

instructor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

in front of Mardom's Park, Pajouhesh Square,

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۸۷

Phone

+98 81 3838 0579

Email

faridehkazemi21@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farideh Kazemi

Position

instructor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

in front of Mardom's Park, Pajouhesh Square,

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۸۷

Phone

+98 81 3838 0579

Email

faridehkazemi21@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be available

When the data will become available and for how long

Access starts 1 year after the article is published

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

To perform meta-analysis

From where data/document is obtainable

Corresponding Author

What processes are involved for a request to access data/document

It will be available within a week after receiving the email and investigating the reason for the individual request

Comments