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)

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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
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Pasdaran Ave
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6517997178
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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
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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
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
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Midwifery
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Person responsible for updating data

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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