Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of implementing a dignity-based maternity care program versus control group on fear of childbirth and childbirth satisfaction among mothers referring to the labor and delivery unit: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of implementing a dignity-based maternity care program versus control group on fear of childbirth and childbirth satisfaction among mothers referring to the labor and delivery unit

Design

This is a single-blind randomized clinical trial with a control group with parallel groups, in which 62 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Fatemieh Hospital in Hamadan, involving 62 eligible mothers referring to the labor and delivery unit. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18–45 years, Primiparity (first-time mother), Gestational age of 37–42 weeks, Planned vaginal delivery, Singleton pregnancy, Normal, low-risk pregnancy, Exclusion Criteria: History of miscarriage or stillbirth, History of infertility, Any chronic medical conditions, Psychiatric disorders, Birth of an infant with an Apgar score of less than 7 at 5 minutes

Intervention groups

Intervention group: Routine clinical care standard in the labor and delivery unit, supplemented by a "maternal dignity-based" care program—implemented from admission through discharge Control Group: Routine clinical care standard in the labor and delivery unit

Main outcome variables

Primary outcome: Fear of childbirth score, Maternal satisfaction score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N628**
Registration date: **2026-11-06, 1405/08/15**
Registration timing: **prospective**

Last update: **2026-11-06, 1405/08/15**
Update count: **0**

Registration date

2026-11-06, 1405/08/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-01, 1405/09/10

Expected recruitment end date

2027-05-31, 1406/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of implementing a dignity-based maternity care program versus control group on fear of childbirth and childbirth satisfaction among mothers referring to the labor and delivery unit: a single-blind randomized clinical trial

Public title

Effect of implementing a dignity-based maternity care program versus control group on fear of childbirth and childbirth satisfaction among mothers referring to the labor and delivery unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18–45 years, Primiparity (first-time mother), Gestational age of 37–42 weeks, Planned vaginal delivery, Singleton pregnancy, Normal, low-risk pregnancy,

Exclusion criteria:

History of miscarriage or stillbirth, History of infertility, Any chronic medical conditions, Psychiatric disorders, Birth of an infant with an Apgar score of less than 7 at 5 minutes

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a single-blind study.

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

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2026-10-31, 1405/08/09

Ethics committee reference number

IR.UMSHA.REC.1405.621

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

F40.232

ICD-10 code description

Fear of other medical care

Primary outcomes

1

Description

Fear of childbirth score

Timepoint

At the time of entry into the study and two hours postpartum

Method of measurement

Based on the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ)

2

Description

Maternal satisfaction score regarding the childbirth

experience

Timepoint

At the time of entry into the study and two hours postpartum

Method of measurement

Based on the Childbirth Experience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine clinical care standard in the labor and delivery unit, supplemented by a "maternal dignity-based" care program—implemented from admission through discharge (consisting of four phases: 1) Admission (respectful treatment, privacy maintenance, provision of clear information, and obtaining informed consent); 2) During labor (continuous emotional support, maternal involvement in decision-making, provision of oral fluids—unless medically contraindicated—offering pain relief methods, and encouraging position changes while avoiding the supine position); 3) Birth phase (continuous support and encouragement to choose a suitable birthing position); and 4) Postpartum (providing information regarding the condition of the mother and newborn, skin-to-skin contact, support for early initiation of breastfeeding, and emotional support for the mother)

Category

Treatment - Other

2

Description

Control Group: Routine clinical care standard in the labor and delivery unit

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan

Full name of responsible person

Zahra Karami

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Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Zahra Karami

Position

Midwifery Student

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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