

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Examining effect of a companion midwife on Fear of Childbirth and labor Satisfaction, and Subsequent Fertility Intention Among Pregnant Women referring to selected hospitals of Shiraz University of Medical Sciences: A randomized clinical trial

Protocol summary

Study aim

To investigate the effect of continuous support provided by a companion midwife, compared with routine maternity care, on fear of childbirth, childbirth satisfaction, and intention for future childbearing among pregnant women attending selected hospitals affiliated with Shiraz University of Medical Sciences.

Design

A randomized, controlled, parallel-group clinical trial. Participants will be allocated to the intervention and control groups using block randomization. Owing to the nature of the intervention, blinding of participants and care providers is not feasible; however, the outcome assessor and data analyst will be blinded to group allocation.

Settings and conduct

The study will be conducted at Hafez Hospital and Shoushtari Maternity Hospital in Shiraz. Participants will be randomly allocated to two groups. The intervention group will receive companion midwife support from the onset of active labour until childbirth, while the control group will receive routine care. Outcomes will be assessed six weeks postpartum.

Participants/Inclusion and exclusion criteria

Participants will be Iranian pregnant women aged 18–40 years with a planned singleton pregnancy, gestational age of 37–42 weeks, spontaneous onset of labour, and cephalic presentation who provide written informed consent. Participants will be excluded if obstetric complications affecting normal labour occur, if they withdraw from the study, or if the questionnaires are completed incompletely.

Intervention groups

Intervention group: Routine intrapartum care plus continuous support provided by a companion midwife from the active phase of labour until childbirth. Control

group: Routine intrapartum care according to hospital protocol without companion midwife support.

Main outcome variables

Fear of childbirth, childbirth satisfaction, and intention for future childbearing at six weeks postpartum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260722070300N1**

Registration date: **2026-08-01, 1405/05/10**

Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**

Update count: **0**

Registration date

2026-08-01, 1405/05/10

Registrant information

Name

Zahra Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

momymidwife@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-22, 1405/05/31

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining effect of a companion midwife on Fear of Childbirth and labor Satisfaction, and Subsequent Fertility Intention Among Pregnant Women referring to selected hospitals of Shiraz University of Medical Sciences: A randomized clinical trial

Public title

Examining effect of a companion midwife on Fear of Childbirth and labor Satisfaction, and Subsequent Fertility Intention

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian nationality Willingness to participate voluntarily in the study and provision of written informed consent Maternal age between 18 and 40 years Ability to read and write minimum literacy Singleton and planned pregnancy Gestational age between 37 and 42 weeks Spontaneous onset of labor Cephalic fetal presentation

Exclusion criteria:

No history of physical illnesses or psychiatric disorders that could interfere with the labor process No use of psychiatric medications or illicit drugs including both traditional and synthetic substances

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 68 eligible nulliparous pregnant women will be enrolled after providing written informed consent and completing the baseline assessment. Participants will be randomly allocated in a 1:1 ratio to either the intervention group (n = 34), receiving continuous support from a companion midwife during labour and childbirth in addition to routine care, or the control group (n = 34), receiving routine maternity care only. Block randomization with a fixed block size of four will be used to ensure balanced allocation between the two study groups throughout the recruitment period. The unit of randomization is the individual participant. No cluster or stratified randomization will be applied. The random allocation sequence will be generated before participant

recruitment using a computerized random sequence generator by an independent researcher who is not involved in participant recruitment, intervention delivery, or outcome assessment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). After confirming eligibility, obtaining written informed consent, and completing participant enrolment, the corresponding envelope will be opened sequentially to reveal the group assignment. Therefore, the researcher responsible for participant recruitment will remain unaware of the allocation sequence until enrolment has been completed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Unit 6, Ahura Building, Alley 2, Shimi Giah Street

City

Shiraz

Province

Fars

Postal code

7188854595

Approval date

1994-02-01, 1372/11/12

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1405.033

Health conditions studied**1****Description of health condition studied**

Fear of Childbirth and ,labor Satisfaction, and Subsequent Fertility Intention

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fear of Childbirth

Timepoint

Baseline before the intervention, prior to the onset of labour and 24–48 hours after childbirth

Method of measurement

Hartmann Childbirth Attitude Questionnaire

Secondary outcomes**1****Description**

Childbirth satisfaction

Timepoint

At 12 to 24 hours postpartum

Method of measurement

Mackey Childbirth Satisfaction

2**Description**

Childbearing intention

Timepoint

At 6 weeks postpartum

Method of measurement

Attitudes toward Fertility and Childbearing Scale

Intervention groups**1****Description**

Intervention group: Participants in the intervention group will receive routine hospital maternity care in addition to continuous support from a trained companion midwife throughout the active phase of labor until childbirth. The companion midwife will provide emotional, informational, and physical support, including encouragement, reassurance, breathing guidance, assistance with maternal positioning, massage, and other non-pharmacological pain relief measures

Category

Behavior

2**Description**

Control group: Participants in the control group will receive routine standard intrapartum care according to the hospital protocol and will not receive continuous support from a companion midwife.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

بیمارستان شوشتری

Full name of responsible person

Zahra Mordi

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Mother and Child Hospital, Shariati Street, Beginning of Hang Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

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Vice Chancellor for Research and Technology, 7th Floor, Central Administration Building, Shiraz University of Medical Sciences, Zand Boulevard

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Moradi
Position
Student
Latest degree
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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