Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

+98 71 3654 4759

Email address

momymidwife@gmail.com

Recruitment status

Recruitment complete

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 Womenreferring 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 Singletonand 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
Street address
Mother and Child Hospital, Shariati Street, Beginning of Hang Street
City
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Province
Fars
Postal code
7173775617
Phone
+98 71 3232 4806
Fax
Email
shoushtari@sums.ac.ir
Web page address
https://shoushtari.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Vice Chancellor for Research and Technology, 7th Floor, Central Administration Building, Shiraz University of Medical Sciences, Zand Boulevard
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
mohammadi219@gmail.com
Web page address
https://research.sums.ac.ir/
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
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Zahra Moradi

Position
Student

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Bachelor

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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