

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effectiveness of midwifery continuity of care program on clinical competence of midwifery students and delivery outcomes: A mixed-method Embedded Experimental study

#### Protocol summary

##### Study aim

Determining the effectiveness of using the continuous care program of midwifery students on the clinical competence of midwifery students and childbirth outcomes and explaining the perception of students and mothers about the use of this care program.

##### Design

The study is a mixed- method Embedded Experimental study (primary clinical trial study and qualitative study). The clinical trial has a control group, with a parallel group, randomized, on 62 pregnant women and 29 midwifery students. A block of 4 was used for randomization.

##### Settings and conduct

Health centers and affiliated hospitals of Ahvaz University of Medical Sciences, including Sina and Razi hospitals and affiliated health centers

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Students: 1. Seventh and eighth semester undergraduate students of the state university 2. Willingness to participate in the study Service recipients (pregnant mothers): 1. Pregnant women aged 18 to 40 years 2. Iranian 3. Singleton pregnancy 4. First pregnancy visit (less than 20 weeks of pregnancy) 5. Low-risk pregnancy Exclusion criteria: 1. Having a disease that requires pregnancy care by a specialist. 2. Mental illnesses, including depression 3. Previous caesarean section 4. Use of alcohol and tobacco

##### Intervention groups

Intervention group: Students who provide continue of care from the beginning of pregnancy to 6 weeks postpartum. Pregnant women receiving continue of care by students. Control groups: Students who provide care to women during labor and delivery up to 6 weeks after delivery. Women receiving routine care.

##### Main outcome variables

1. Clinical competence 2. Type of delivery 3. Length of

labor stages 4. The amount of induction 5. Postpartum bleeding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221227056938N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

##### Registration date

2023-01-17, 1401/10/27

##### Registrant information

##### Name

Fatemeh Razavinia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 210 3403

##### Email address

fatemehrazavinia15@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-20, 1401/10/30

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effectiveness of midwifery continuity of care program on clinical competence of midwifery students and delivery outcomes: A mixed- method Embedded Experimental study

**Public title**  
The effectiveness of midwifery continuity of care program on clinical competence of midwifery students

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Seventh and eighth semester undergraduate students of the state university Willingness to participate in the study Pregnant women aged 18 to 40 years Iranian Singleton pregnancy First pregnancy visit (less than 20 weeks of pregnancy) Low risk pregnancy  
**Exclusion criteria:**  
Having a disease that requires pregnancy care by a specialist. Mental illnesses including depression Previous caesarean section Use of alcohol and tobacco

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

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **62**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Allocation of mothers in this study is accessible and easy. Students are allocated in blocks of four. Five blocks of four and 3 blocks of 3 will be formed. From each block of four, two people will be in the intervention group and two people will be in the control group, and from each block of three, two people will be in the intervention group and one person will be in the control group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Participants and students as caregivers do not know how to study and in which group

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Golestan

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

37333-61349

#### Approval date

2023-01-06, 1401/10/16

#### Ethics committee reference number

IR.AJUMS.REC.1401.460

## Health conditions studied

### 1

#### Description of health condition studied

Examining the clinical competence of students

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Clinical competence

#### Timepoint

after the study

#### Method of measurement

Questionnaire made by the researcher

### 2

#### Description

Type of delivery

#### Timepoint

During the study

#### Method of measurement

Checklist

### 3

#### Description

The length of labor stages

#### Timepoint

During the study

#### Method of measurement

Checklist

### 4

#### Description

The amount of induction and induction

**Timepoint**

During the study

**Method of measurement**

Checklist

**5**

**Description**

Postpartum bleeding

**Timepoint**

During the study

**Method of measurement**

Checklist

**Secondary outcomes**

**1**

**Description**

Apgar first and fifth minutes

**Timepoint**

During the study

**Method of measurement**

check list

**2**

**Description**

Hospitalization in the neonatal intensive care unit

**Timepoint**

During the study

**Method of measurement**

check list

**3**

**Description**

Start early breastfeeding

**Timepoint**

During the study

**Method of measurement**

check list

**4**

**Description**

Exclusive breastfeeding

**Timepoint**

During the study

**Method of measurement**

check list

**Intervention groups**

**1**

**Description**

Intervention group: provision of continuous of care by students to pregnant women.

**Category**

N/A

**2**

**Description**

Intervention group: Students provide pregnancy continue of care for pregnant women from the beginning of pregnancy to 6 weeks after delivery.

**Category**

N/A

**3**

**Description**

Control group: women who receive routine care.

**Category**

N/A

**4**

**Description**

Control group: Students who provide routine care during labor and delivery and continue care until 6 weeks after delivery.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health Center and Ahvaz Sina and Razi Hospital

**Full name of responsible person**

Parvin Abedi

**Street address**

Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Phone**

+98 911 210 3403

**Email**

fatemehrazavinia15@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Parvin Abedi

**Street address**

Golestan

**City**

Ahvaz

**Province**

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**Grant name**

Ahvaz University of Medical Sciences

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

70

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Parvin Abedi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Golestan

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## Person responsible for scientific inquiries

**Contact**

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Ahvaz University of Medical Sciences

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**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Razavinia

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Phone**

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**Email**

fatemehrazavinia15@gmail.com

## Sharing plan

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

Yes - There is 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**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The implications of the review can be shared

anonymously.

**When the data will become available and for how long**

After completing the study (starting access 6 months after publication)

**To whom data/document is available**

Researchers working in academic and scientific institutions and policy makers.

**Under which criteria data/document could be used**

If you have an official letter from the scientific center

**From where data/document is obtainable**

To printed magazines and indexed sites. Request to the project manager's email

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

Six months after completing the study of the application, the data will be sent to the project manager, if the conditions are met, up to two months.

**Comments**