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

Khouzestan

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

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Province

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61357-15794

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fatemehrazavinia15@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

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Position
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Latest degree
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Midwifery

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Latest degree
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Other areas of specialty/work
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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