Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Leadership and Mentorship Program in Clinical Education of Midwifery Students

Protocol summary

Study aim

Determining the effectiveness of leadership and clinical mentorship programs on the clinical competence of midwifery students and maternal and neonatal outcomes.

Design

This study will be conducted as a clinical trial with a control group as an open trial, with parallel groups, and randomized on 30 students and 420 patients. Simple randomization will be used for randomization.

Settings and conduct

The present study will be conducted in Sina and Taleghani hospitals of Ahvaz city as a randomized clinical trial. At the beginning of the research, in the first two months of the beginning of the semester, the control group, who will be randomly selected, will enter the research and will go through the maternity internship unit according to the usual routine by the relevant trainer, and the clinical training will be in the usual way. After the end of the internship period (which lasts for two months), the students of the intervention group will enter the research. In this group, clinical training will be implemented in the form of mentorship and leadership.

Participants/Inclusion and exclusion criteria

Inclusion criteria for midwifery students: final year midwifery students. For midwifery trainers: have at least a master's degree in midwifery; have at least five years of work experience in a maternity unit. For service recipients: low-risk pregnant women admitted to the maternity hospital for childbirth. Exclusion criteria: guest students, non-staff instructors of Jundishapur University of Medical Sciences, and high-risk pregnancy.

Intervention groups

Mentorship method will be used in the intervention group for midwifery clinical training. And in the control group, midwifery clinical training will be done in a traditional and conventional way according to the usual routine.

Main outcome variables

The main outcome variables include students' clinical competence, and students' satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200111046079N2**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Leila Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3332 2782

Email address

fathi.l@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Leadership and Mentorship Program in Clinical Education of Midwifery Students

Public title

Investigating the effect of Leadership and Mentorship Program in Clinical Midwifery Education

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria for midwifery students: final year midwifery students who want to participate in the study. Inclusion criteria for midwifery trainers: trainers who want to mentoring and educate students. Having a minimum Midwifery Masters Degree Having at least five years of work experience in the maternity unit Inclusion criteria for Service Recipients: low -risk pregnant women are hospitalized in maternity for delivery.

Exclusion criteria:

Guest students, that is, students studying at other universities who have been guest at Jundishapur University for one semester Coaches outside the staff of Jundishapur University of Medical Sciences High-risk pregnancy and labor of child-bearing women

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **14**

Each participant contains students who enter the research, and at least each student is expected to have 14 delivery during the eighth semester. Therefore, the samples of each person participating in this study include pregnant women who will give birth by each student.

Randomization (investigator's opinion)

Randomized

Randomization description

In order to generate the random sequence, simple randomization will be used in such a way that by using a table of random numbers based on the list of names and student numbers of final year midwifery students, people will be randomly placed in two groups A and B. The table of random numbers used in this research will include numbers that will be placed next to each other in rows and columns in the form of five-digit blocks and separately. To use this table, we will assign two-digit codes corresponding to the last two numbers of the student number, such as 01, 02,..., 29, 30, according to the exact size of the sample (30 students). Then the researcher will randomly start from a point to select sample people from the table. For this purpose, the researcher will choose the starting point by closing his eyes and placing the tip of the pen on the table, then she will move in the direction of the row or column until numbers choose the one whose last two digits (i.e. the two digits on the right side of each block of five) are smaller than the sample size (which actually corresponds to the student number of the sample). This process will continue until the sample volume is completed. The first 15 selected codes will belong to group A and the next 15 codes will belong to group B. It should be noted that the nature of two groups A and B is not known in advance. Next to randomly assign the two research groups as well as to concealment random allocation according to the same groups A and B, and according to the corresponding codes in sequentially numbered, opaque, sealed envelopes, by an out -of -study person with no information There is no research goals.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand Ave., Golestan Blvd.,Deputy of research and technology, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

15794 61357

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.AJUMS.REC.1401.372

Health conditions studied

1

Description of health condition studied

Clinical midwifery education

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Midwifery student's clinical competency
Timepoint
After the end of the semester and at the time of the Midwifery Final Test
Method of measurement
Clinical Competence Questionnaire

2

Description
Midwifery students' satisfaction
Timepoint
After the end of the semester and at the time of the Midwifery Final Test
Method of measurement
Satisfaction Questionnaire

Secondary outcomes

1

Description
Type of delivery
Timepoint
After the end of the semester
Method of measurement
Using the Bureau of Delivery

2

Description
perineal status
Timepoint
After the delivery
Method of measurement
Due to the intensity of the perineal area rupture as grade 1,2,3,4

3

Description
Post partum hemmorage
Timepoint
Eight hours after delivery
Method of measurement
Measurement of hematocrit level

4

Description
Apgar score
Timepoint
One minute after delivery and five minutes after delivery
Method of measurement
Based on clinical evaluation and examination of skin color, muscle tone, crying, heart rate, response to catheter stimulation

5

Description
Breastfeeding
Timepoint
The first hour after childbirth
Method of measurement
Breastfeeding or not?

Intervention groups

1

Description
Control group: In the control group, in the first two months of the beginning of the semester, the internship program of the maternity hospital will be implemented according to the usual routine in the previous semesters based on the program presented by the director of the midwifery department,.The clinical instructors, according to their usual training method that they used to train students The clinical training of the students will take place in the maternity hospital, and it is very clear that the interventions related to the mentorship program will not be implemented in the control group. Finally, the evaluation of the clinical competence of the students in the control group will be carried out by the trainers based on the trainer's personal opinion as usual. We need to mention that since the communication of students with each other in the places of the university, dormitory, hospital, etc. could have an effect on the results of the research, therefore, after random allocation, the group that is selected first during random concealment will be selected automatically. They will enter the control group and in the first two months of the study, the control group will start and the next group will enter the study as the intervention group in the next two months.
Category
Other

2

Description
Intervention group: In the intervention group, in the next two months of the semester, the internship program of the maternity hospital will be implemented based on the mentorship training method, and the clinical trainers will train the students after passing the clinical training workshops. It should be noted that the items related to the mentorship program will be determined after reviewing the texts and the Delphi technique. Finally, the evaluation of the mentorship program will be done using the Kirk patrick evaluation model.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital
Full name of responsible person
Mina Iravani
Street address
Shahid 1 St, Imam Ali Square, Ayatollah Behbahani Highway
City
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Province
Khouzestan
Postal code
6199117111
Phone
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Email
Sinahospital.ch@ajums.ac.ir
Web page address
https://hsina.ajums.ac.ir/fa-IR/hsina.ajums.ac/5047/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%D9%8A

2

Recruitment center
Name of recruitment center
Ayatollah Taleghani accident and burn hospital
Full name of responsible person
Mina Iravani
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Saadat Square, phase two of Padadshahr
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https://htaleghani.ajums.ac.ir/fa-IR/htaleghani.ajums.ac/8577/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%D9%8A

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sahand Jorfi
Street address
Esfand Ave., Golestan Blvd.,Deputy of research and technology, Ahvaz, Iran
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+98 61 3336 1544
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jorfi-s@ajums.ac.ir
Grant name
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
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
Ahvaz University of Medical Sciences
Full name of responsible person
Mina Iravani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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Associate professor

Latest degree

Ph.D.

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data and results of the research will be provided to Jundishapur University of Medical Sciences Ahvaz and Sina and Taleghani Hospitals

When the data will become available and for how long

It will be possible to access the research documents six months after the final statistical analysis and the end of the qualitative phase of the study.

To whom data/document is available

The data will be available only for the use of researchers of academic institutions.

Under which criteria data/document could be used

In order to develop research in the field of clinical education of medical sciences and mentorship

From where data/document is obtainable

In order to receive the data, people can refer to the main executive of the project, Dr. Mina Irvani, a member of the academic staff of Jundishapur University of Medical Sciences, Ahvaz.

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

After obtaining the necessary permits from the Jundi Shapur University of Medical Sciences and the Vice-Chancellor of Research and Technology of this university, the applicant can proceed to receive the documents.

Comments