Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Design and evaluation of a virtual reality-based neonatal resuscitation simulator

Protocol summary

Study aim

1. Evaluating the effectiveness of a 360-degree video-based neonatal resuscitation simulator and virtual reality headset on improving the theoretical knowledge of midwifery students 2. Evaluating the effectiveness of a 360-degree video-based neonatal resuscitation simulator and virtual reality headset on improving the clinical skills of midwifery students 3. Determining the average sense of presence of users after using a 360-degree video-based neonatal resuscitation simulator and virtual reality headset 4. Evaluating the usability of a 360-degree video-based neonatal resuscitation simulator and virtual reality headset

Design

A single-blind, two-arm, parallel-group RCT will be conducted among 66 midwifery students using 1:1 block randomization (block sizes of 4 and 6).

Settings and conduct

This phase will evaluate users' reactions (presence and usability) and learning (knowledge and clinical skills) based on the Kirkpatrick model among undergraduate midwifery students at Tabriz University of Medical Sciences (2027–2028). Outcome assessors and data analysts will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Bachelor of Midwifery students at Tabriz University of Medical Sciences Exclusion criteria: Physical or movement problems that prevent independent use of the virtual reality system.

Intervention groups

Intervention group: Virtual reality neonatal resuscitation simulator in addition to the usual training. The intervention will be delivered in four one-hour sessions over two weeks. In each session, students will be exposed to progressive scenarios based on the standard neonatal resuscitation algorithm in a virtual reality simulator environment. Control group: Traditional education only

Main outcome variables

Theoretical knowledge of neonatal resuscitation; Clinical skills in neonatal resuscitation; Sense of presence; Simulator usability.

General information

Reason for update

Acronym

VR-NRP Simulator

IRCT registration information

IRCT registration number: **IRCT20120718010324N91**
Registration date: **2026-11-06, 1405/08/15**
Registration timing: **prospective**

Last update: **2026-11-06, 1405/08/15**
Update count: **0**

Registration date

2026-11-06, 1405/08/15

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-09-23, 1406/07/01

Expected recruitment end date

2029-01-20, 1407/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation of a virtual reality-based neonatal resuscitation simulator

Public title

Design and Evaluation of an Innovative Neonatal Resuscitation Training Method Using Virtual Reality Technology

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Bachelor of Midwifery students at Tabriz University of Medical Sciences

Exclusion criteria:

Having physical or movement problems that prevent independent use of the virtual reality system.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two intervention and control groups using a block random allocation method (block size 4 and 6) with an allocation ratio of 1:1. For allocation concealment, opaque, sealed, and sequentially numbered envelopes will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the educational nature of the intervention, blinding of participants and intervention providers is not possible. However, to reduce the possibility of bias, the outcome assessor (who will administer the OSCE) and the data analyst will be blinded to the group allocation of participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research Department, Third Floor, Central Construction No. 2, Tabriz University of Medical Sciences, Golgasht St., Azadi Ave., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2026-10-24, 1405/08/02

Ethics committee reference number

IR.TBZMED.REC.1405.535

Health conditions studied

1

Description of health condition studied

Neonatal resuscitation training

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluating the effectiveness of a 360-degree video-based neonatal resuscitation simulator and virtual reality headset on improving midwifery students' theoretical knowledge in neonatal resuscitation

Timepoint

1. Initial theory knowledge test or pre-test 2. Post-test of theory knowledge 3. Retention test of theory knowledge after 1 month

Method of measurement

Standard questions at the end of each chapter of the ninth edition of the Neonatal Resuscitation Textbook

2

Description

Evaluating the effectiveness of a 360-degree video-based neonatal resuscitation simulator and virtual reality headset on improving the clinical skills of midwifery students in neonatal resuscitation

Timepoint

1. Initial clinical skills test or pre-test 2. Post-test of clinical skills 3. Clinical skills retention test after 1 month

Method of measurement

Standard observation checklist based on NRP guidelines by a trained assessor

Secondary outcomes

1

Description
Sense of presence in the virtual reality environment
Timepoint
Immediately after the intervention (intervention group only)
Method of measurement
Igroup Presence Questionnaire; IPQ

2

Description
Usability of the virtual reality simulator
Timepoint
Immediately after the intervention (intervention group only)
Method of measurement
System Usability Scale; SUS

Intervention groups

1

Description
One week before the intervention, participants' sociodemographic data and neonatal resuscitation knowledge and skills will be assessed. Following an introductory session on VR headset use, the intervention will be delivered in four one-hour sessions over two weeks. Students will perform progressive neonatal resuscitation scenarios based on the NRP algorithm in the VR simulator. Their performance will be recorded, immediate feedback provided, and scenarios repeated to reinforce learning and improve clinical skills.
Category
Treatment - Devices

2

Description
Control group: The control group will receive only the usual training.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences
Full name of responsible person
Roghayyeh Valizadeh
Street address
South Shariati St., School of Nursing and Midwifery, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person

Mojgan Mirghafourvand

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the confidentiality and privacy of the participants' personal information, we do not plan to share the individual participant data.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available