Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Simulation-Based Education on Nursing Students’ Knowledge, Performance, Satisfaction and Self-Confidence in the Blood Transfusion Process and the Management of Related Complications

Protocol summary

Study aim
Determining the effect of simulation-based training on nursing students' knowledge, performance, satisfaction, and self-confidence in the blood transfusion process and management of its associated complications

Design
A controlled, single-blind, randomized, block-based clinical trial on 60 nursing students.

Settings and conduct
Study environment at Islamic Azad University, Karaj, 1404. Sample of 60 nursing students (years 4-6), randomly blocked (by year, gender, GPA) into intervention and control groups, single-blind (ratings via standard clinical performance checklist by independent evaluators with no intervention role).

Participants/Inclusion and exclusion criteria
Entry criteria: Nursing students in years 4-6, at least two internships, willing to participate. Exit criteria: Missing a transfusion workshop before the study, absence in one session, not completing questionnaires, inactive participation, illness affecting results, or withdrawal for any reason.

Intervention groups
The test group receives lecture training (theory) and a simulation-based training program (practical).

Main outcome variables
Awareness, performance; satisfaction and self-confidence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250524065863N1**
Registration date: **2025-07-21, 1404/04/30**
Registration timing: **prospective**
Last update: **2025-07-21, 1404/04/30**
Update count: **0**

Registration date
2025-07-21, 1404/04/30

Registrant information

Name
zohre jafareepoor

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4480 0508

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vjafareepoor@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-31, 1404/05/09

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Simulation-Based Education on Nursing Students’ Knowledge, Performance, Satisfaction and Self-Confidence in the Blood Transfusion Process and the Management of Related Complications

Public title
The Effect of Simulation-Based Education on Nursing Students’ Knowledge, Performance, Satisfaction and Self-

Confidence in the Blood Transfusion Process and the Management of Related Complications

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Nursing student, 4th-6th semester having at least two semesters of teaching experience willingness to participate in research

Exclusion criteria:

Participate in a blood transfusion workshop before conducting the research. Failure to complete questionnaires or actively participate in the research process Suffering from any physical or mental illness during the study that could affect the results of the study. Withdrawing from participation in the study for any reason

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a two-group parallel educational trial with a 1:1 allocation ratio. Sixty nursing students in semesters 4-6 who meet the inclusion criteria will be enrolled in the study after providing informed consent and will be assigned to two groups: ;intervention; (theoretical training + simulation-based training) and ;control; (theoretical training only with similar content). The unit of randomization is the ;individual.; Allocation concealment is performed using sequentially numbered; opaque; sealed; and consecutively numbered envelopes within each stratum. After generating the list; an independent statistician prints a group code sheet (A = intervention; B = control) for each sequence number; places it in an envelope; seals the seam; signs the seal; and keeps the envelopes in a locked box. After registering and coding each student and completing the consent form; the recruitment officer (who does not have access to the master list) opens the next envelope from the same stratum in the presence of a witness and records the group code on the ;Allocation Registration Form; (envelope number; date; officer's signature; witness's signature). In this way; the group is not predictable until the moment the envelope is opened.

Blinding (investigator's opinion)

Single blinded

Blinding description

Complete blinding of participants and instructors is not feasible due to the nature of the educational intervention (presence or absence of simulation). Therefore; the design is a single-blind type: the outcome assessor (evaluating OSCE test scores and awareness scores) and the statistical analyst are blinded to group allocation. To implement blinding; only anonymous student codes are recorded on all questionnaires and OSCE sheets; and students commit in writing before the test not to disclose their training modality to the assessor; following written instructions. Data entry is performed by an individual who does not have access to the group decoding table. The data are provided to the analyst in groups labeled "Group B" and "Group A;" and after initial analysis and database locking; the decoding is carried out. To prevent "between-group contamination;" simulation sessions are held at separate times; and students in the intervention group sign a written commitment not to share any scenario details with others until after the post-test. The theoretical content (slides; instructor; duration) remains identical in both groups; so the only variable difference is "adding simulation." Practical performance assessments are conducted using a standard OSCE station (15 minutes) and a validated checklist (21 items; including 4 critical items) both before and after the intervention in each group. The evaluator does not participate in the educational intervention and is unaware of participant group allocation. To monitor the stability of the assessment; a second blinded evaluator randomly attends 20% of the assessments, and the agreement coefficient (Kappa) is calculated; if $\kappa < 0.75$; re-training is conducted. In case of unintentional group disclosure (e.g.; a student verbally revealing their training method); the incident is recorded in the "Blinding Breach Incident Form;" and sensitivity analysis is performed excluding that case. The randomization list is securely stored in encrypted form with an independent statistician and is only released after database locking. All procedures (sequence generation; envelope preparation; opening; recording; and storage) are documented within an standard operating procedure; which can be provided upon request to the ethics committee.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Karaj Azad University

Street address

No.5559, 22 Bahman , Bagh Feyz, St Ashrafi Esfahani

City

Tehran

Province

Tehran

Postal code

1473788633

Approval date

2025-07-05, 1404/04/14

Ethics committee reference number

IR.IAU.K.REC.1404.073

Health conditions studied

1

Description of health condition studied

Clinical simulation, blood transfusion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Awareness of nursing students

Timepoint

Before intervention and after intervention

Method of measurement

Blood transfusion awareness questionnaire

2

Description

Nursing student transportation

Timepoint

Before intervention and after intervention

Method of measurement

Checklist for evaluating nursing students' performance in the blood transfusion process

3

Description

Satisfaction and self-confidence of nursing students

Timepoint

Before intervention and after intervention

Method of measurement

Satisfaction and self-confidence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention :Intervention: Simulation-based training for the intervention group will be held after a 4-hour lecture session. Implementation of simulation scenarios: Given the number of students in the intervention group (30), the scenario will be held over three days, one in the morning and one in the evening. To perform the intervention, low-realism simulation equipment is used, which includes a clinical skills center station for the first encounter (care before, during, and after blood transfusion) and a second station (for dealing with blood transfusion complications).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Karaj Branch

Full name of responsible person

zohre jafareepoor

Street address

No.5559, Spring building, between Chamran and Baharan, Amir Ebrahim St.22 Bahman St, Bagh Feyz, Ashrafi Esfahani

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Email

jafareepoorvenus@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zohre jafareepoor

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No.5559, Spring building, between Chamran and Baharan, Amir Ebrahim St.22 Bahman St, Bagh Feyz, Ashrafi Esfahani

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Zohre jafareepoor
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
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
Yes - There is a plan to make this available
Title and more details about the data/document
Only the research team has permission to access the data.
When the data will become available and for how long
up to five years
To whom data/document is available
It can only be used for study and for the needs of big data studies for others.
Under which criteria data/document could be used
Based on the journal's request, the reviewer and the researcher will be sent the big data.

From where data/document is obtainable

Tehran; Ashrafi Esfahani; Bagh-e Feyz; 22 Bahman Street; Amir Ebrahim Street; between Baharan and Chaman; Bahareh Building; Unit 5559; Zohre JafareePoor.

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

Based on the journal's request, the reviewer and the researcher will be sent the big data.

Comments