Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing virtual and real simulators of the operating room environment for managing nursing students' self-confidence and anxiety in the first experience of operating room

Protocol summary

Study aim
Comparing virtual and real simulators of the operating room environment for managing nursing students' self-confidence and anxiety in the first experience of operating room

Design
Nursing students will be considered non-randomly in the first semester as the control group and nursing students in the second semester as the intervention group. In the intervention group, an operating room simulator will be used for training.

Settings and conduct
The virtual simulator developed in Hazrat Fatemeh (S) Shiraz College of Nursing and Midwifery will be evaluated.

Participants/Inclusion and exclusion criteria
1. Nursing undergraduate students 2. Choosing a study unit in the field of adults 1 3. Willingness to participate in the study

Intervention groups
In the intervention group (nursing students in the second semester), training before attending the operating room is based on the use of virtual simulation (virtual tour of the operating room), which is available to them via mobile phone two days before entering the operating room. will be placed and students will interact with the operating room environment through the simulator.

Main outcome variables
self-confidence؛ anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240608062038N2**
Registration date: **2024-06-18, 1403/03/29**
Registration timing: **prospective**

Last update: **2024-06-18, 1403/03/29**
Update count: **0**

Registration date
2024-06-18, 1403/03/29

Registrant information

Name
Somayeh Gheisari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3647 4254

Email address
somayeh.gh65@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-07-21, 1404/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing virtual and real simulators of the operating room environment for managing nursing students' self-confidence and anxiety in the first experience of operating room

Public title

Comparing virtual and real simulators of the operating room environment for managing nursing students' self-confidence and anxiety in the first experience of operating room

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Nursing undergraduate students Choosing a study unit in the field of adults 1 Student of Hazrat Fatemeh (S) Faculty of Nursing and Midwifery, Shiraz Willingness to participate in the study

Exclusion criteria:

Having previous experience of being in the operating room environment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Faculties of nursing and midwifery, management and medical information - Shiraz University of Medica

Street address

Namazi square- Faculty of Nursing

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2024-03-11, 1402/12/21

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1403.006

Health conditions studied

1

Description of health condition studied

Education of students

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

self-confidence

Timepoint

Before the start of training - the first day of training - the end of training

Method of measurement

Rosenberg self-esteem scale

2

Description

anxiety

Timepoint

Before the start of training - the first day of training - the end of training

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: After explaining the objectives of the research and obtaining consent from the participants, the students of both the control and intervention groups will complete the study questionnaires. Then the training in the intervention group will be done in a virtual way. In the intervention group, the training is based on the use of virtual simulation (virtual tour of the operating room), which will be provided to them via mobile phone two days before entering the operating room, and the students will familiarize themselves with the operating room environment through the simulator. will interact. After the educational interventions, the students of both the intervention and control groups enter the real operating room and perform their routine tasks in the internship. At the end of the first day, both groups will complete the study questionnaires. Finally, on the last day of the study, the questionnaires of this study will be completed again by the students of both groups.

Category

Other

2

Description
Control group: After explaining the objectives of the research and obtaining consent from the participants, the students of both the control and intervention groups will complete the study questionnaires. Then the training will be done in the control group based on the usual method and in the intervention group in a virtual method. In this way, two days before entering the operating room, the students of the control group, by attending the practical environment (real simulation) according to the usual routine, receive the necessary explanations about the environment of the operating room and the relevant rules from their professor. After the educational interventions, the students of both the intervention and control groups enter the real operating room and perform their routine tasks in the internship. At the end of the first day, both groups will complete the study questionnaires. Finally, on the last day of the study, the questionnaires of this study will be completed again by the students of both groups.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz School of Nursing

Full name of responsible person
Mehdi Hasanshahi

Street address
Namazi square - Faculty of Nursing

City
Shiraz

Province
Fars

Postal code
71936-13119

Phone
+98 71 3647 4254

Email
mhdi.hasanshahi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohamad Hashem Hashempour

Street address
Shiraz - Zand St. - next to Red Crescent - central building of Shiraz University of Medical Sciences - 7th floor

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3212 2430

Email
vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mehdi Hasanshahi

Position
Instructor of operating room group

Latest degree
Master

Other areas of specialty/work
Others

Street address
Namazi square - Faculty of Nursing

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mehdi Hasanshahi

Position

Instructor of operating room group

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mehdi Hasanshahi

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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

Yes - There is a plan to make this available

Title and more details about the data/document

1- Obtaining the code of ethics from the Research Vice-Chancellor of Shiraz University of Medical Sciences 2- Obtaining a letter of introduction from the Research Vice-Chancellor of Shiraz University of Medical Sciences and presenting it to the Educational Vice-Chancellor of Shiraz University of Medical Sciences 3- Providing an explanation to all research units about the objectives and how to implement it 4- Obtaining informed consent at the beginning of the study from the research units 5- Keeping in mind the willingness of the research units to participate in the research and informing them about the possibility of withdrawing at any stage of the study without any penalty or impact on their academic evaluation 6- Reassuring the research units that the information obtained is confidential and only general results will be published 7- Respecting the rights of colleagues in all publications resulting from this research 8- Adhering to the principles of Helsinki ethics

When the data will become available and for how long

The storage period of study data is about two years.

To whom data/document is available

Research units

Under which criteria data/document could be used

If the research participants request to know their educational status

From where data/document is obtainable

Executive in charge of the research project

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

The contact number and email of the responsible executive will be provided to the participants.

Comments