Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effectiveness of a pediatric airway management training program delivered through two methods of a role-playing simulation and an escape room-based serious game on knowledge and performance of students at Guilan University of Medical Sciences by using an interdisciplinary teaching approach: A randomized controlled trial

Protocol summary

Study aim

Determining and comparing the impact of an educational program on air traffic management for children using two methods: role-playing combined with simulation and serious play based on escape rooms, on the knowledge and performance of students at Guilan University of Medical Sciences with an interdisciplinary teaching approach.

Design

Randomized controlled trial with a control group, using parallel groups, unblinded, randomized, on 90 students. Sealed Envelope Ltd's online randomization service was used for randomization.

Settings and conduct

The context for conducting the research and collecting data is provided by the Shahid Beheshti School of Medicine, Nursing, and Midwifery in Rasht, and the Clinical Skills Center of the Shahid Beheshti School of Nursing and Midwifery in Rasht.

Participants/Inclusion and exclusion criteria

Entry criteria: Willingness to participate in research. Students in the 6th and 7th years of the professional doctoral program in medicine 4th year nursing students 2nd, 3rd, and 4th year students of the continuous bachelor's program in emergency medicine Exit criteria: Absence in any of the training sessions. Incomplete completion of the information gathering tools in any of the screening stages, pre-test, or post-test.

Intervention groups

Intervention Group One (Role-Playing with Simulation)Intervention Group Two (serious game based on escape room) Control Group

Main outcome variables

Role-playing group with simulation Serious game group based on escape room Control group Knowledge Performance Satisfaction with the teaching method

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160102025809N3**
Registration date: **2025-07-13, 1404/04/22**
Registration timing: **prospective**

Last update: **2025-07-13, 1404/04/22**
Update count: **0**

Registration date

2025-07-13, 1404/04/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 8512

Email address

zahra_taheri@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of a pediatric airway management training program delivered through two methods of a role-playing simulation and an escape room-based serious game on knowledge and performance of students at Guilan University of Medical Sciences by using an interdisciplinary teaching approach: A randomized controlled trial

Public title

Comparing the effectiveness of a pediatric airway management training program delivered through two methods of a role-playing simulation and an escape room-based serious game on knowledge and performance of students at Guilan University of Medical Sciences by using an interdisciplinary teaching approach: A randomized controlled trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in research. the 6th and 7th years of professional medical students Fourth-year nursing undergraduate students Students in the 2nd, 3rd, and 4th years of continuous undergraduate medical emergency studies.

Exclusion criteria:

Experience of the company in the workshop on air way management for children Experience in managing airways in children Being employed in emergency and ICU

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

All selected students will be classified using stratified block randomization with block sizes of three and evenly (in a 1:1:1 ratio) divided into three groups: intervention group one (role-playing with simulation; number=30), intervention group two (serious game based on escape room; number=30), and control group (number=30). To generate a list of randomization, the online randomization service Sealed Envelope Ltd is used. The concealment of allocation is done using opaque envelopes that are sealed with a random sequence.

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 in Guilan University of Medical Sciences

Street address

Deputy of Research and Technology ,Old Building, School of Health, Shahid Siadati Avenue, Namjoo St.Guilan,Rasht,Iran

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2025-06-18, 1404/03/28

Ethics committee reference number

IR.GUMS.REC.1404.130

Health conditions studied

1

Description of health condition studied

pediatric airway management

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of the children's airway management knowledge in the knowledge questionnaire.

Timepoint

Immediately after the intervention

Method of measurement

The questionnaire consists of 30 items that assess students' knowledge regarding airway management in children across 5 domains (Table 4). Each item is answered based on a 4-option scale (one correct answer, two incorrect answers, and one 'I don’t know' option). A correct answer receives a score of +1, an incorrect answer receives a score of -0.5, and an 'I don’t know' answer receives a score of zero.

2

Description

Children's airway management performance score based on the checklist

Timepoint

Immediately after the intervention

Method of measurement

The performance checklist consists of 56 items that evaluate performance across 3 domains (Table 5). Each item contains two options: Yes and No. If the individual correctly performs the clinical process, the Yes option is marked; if unable to perform correctly, the No option will be completed by the evaluator.

3

Description

The level of satisfaction with the teaching method in the satisfaction questionnaire

Timepoint

Immediately after the intervention

Method of measurement

The satisfaction questionnaire comprises 8 items that measure students' satisfaction regarding the teaching method used for airway management in children. Each item is answered based on a 5-option scale: Strongly Disagree (1), Disagree (2), Neutral (3), Agree (4), and Strongly Agree (5).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention Group One (Role-Playing with Simulation): In this group, educational content is presented to students through role-playing combined with simulation, done by the researcher and supervised by faculty members, in-person during a one-hour session. For this purpose, clinical scenarios are initially developed based on the educational goals and content. A 30-minute introductory session is first held in-person, during which the course outline, educational objectives, nature of the intervention, characteristics, implementation process, and rules are thoroughly explained to the students. Then, students are divided into groups of six, consisting of two medical students, two nursing students, and two emergency medicine students, with one member chosen by group consensus to act as the representative. The groups will proceed to five different stations when the bell rings, where each station contains a scenario involving a hypothetical child in need of airway management. The scenario is read by the group representative, and then the group members negotiate and discuss to reach a common solution. At each station, groups will have a limited role-playing opportunity of 10 minutes based on the scenario. At the end of the designated time, the performance, strengths, and weaknesses of the group will be identified and addressed by the facilitator.

Category

N/A

2

Description

Intervention group: Intervention Group: Intervention Group Two (Serious Game Based on Escape Room): Students in this group will receive educational content through a serious game based on an escape room. For this purpose, an initial 30-minute face-to-face briefing session will be held, during which the course plan, educational objectives, nature of the intervention, features, implementation process, and rules will be thoroughly explained to the students. Then, students will be divided into groups of six, with each group consisting of two medical students, two nursing students, and two paramedic students. Each group enters the escape room(s) to solve the designed challenges using their teamwork skills and knowledge. In each room, there is a scenario involving a hypothetical child who requires airway management. Each scenario consists of several stages and puzzles that group members must solve collaboratively at each stage, which includes selecting the appropriate technique, choosing the necessary equipment, and determining the size of the equipment needed for the hypothetical child. After solving each puzzle at each stage, they receive a clue for the next stage until they rescue the patient. Groups have a limited time of 30 to 60 minutes to solve the puzzles and ultimately rescue the patient and find the key to exit the room. It is worth mentioning that each group has one chance in each room and it cannot be repeated. In case of confusion among learners, facilitators present in each room will provide guidance. The escape room(s) used in this research are known as Pediatric Avengers - Airway Challenge and will be designed by a team consisting of a researcher and three faculty members (a supervisory professor and consultant colleagues). The design of these rooms is based on the escapeED model proposed by Clark and colleagues and includes 6 key elements: (1) learners, (2) goals, (3) theme, (4) puzzles, (5) equipment, and (6) assessment.

Category

N/A

3

Description

Control group: In the control group, no additional intervention will take place (training in the control group will be conducted as general training: including lectures, practical stations, and the use of models).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
The medical, nursing, and midwifery schools of Shahid Beheshti University in Rasht, and the Center f

Full name of responsible person
Zahra Taheri Ezbarami

Street address
Shahid Beheshti Highway - Daneshjoo Street

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 13 3255 3202

Fax
+98 13 3255 0097

Email
nursing@gums.ac.ir

Web page address
https://nmr.gums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Ramiar Farzan

Street address
In front of 17 Shahrivar Hospital, Siadati St., Namjoo St

City
Rasht

Province
Guilan

Postal code
41446-66949

Phone
+98 13 3333 5821

Email
research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Guilan University of Medical Sciences Rasht Iran

Proportion provided by this source
50

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
Rasht University of Medical Sciences

Full name of responsible person
zahra taheri ezbarami

Position
faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing and Midwifery School of Shahid Dr. Beheshti, Hamidyan Shahrak, Shahid Dr. Beheshti Ave., Rasht, Guilan, IRAN

City
Rasht

Province
Guilan

Postal code
41469-39841

Phone
+98 13 3355 5058

Fax
+98 13 3355 0097

Email
zahra_taheri@gums.ac.ir

Web page address
http://www.gums.ac.ir/nmr

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
zahra taheri ezbarami

Position
faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing and Midwifery School of Shahid Dr. Beheshti, Hamidyan Shahrak, Shahid Dr. Beheshti Ave., Rasht, Guilan, IRAN

City
Rasht

Province
Guilan

Postal code
41469-39841

Phone
+98 13 3355 5058

Fax

+98 13 3355 0097

Email

zahra_taheri@gums.ac.ir

Web page address

http://www.gums.ac.ir/nmr

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

zahra taheri ezbarami

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School of Shahid Dr. Beheshti, Hamidyan Shahrak, Shahid Dr. Beheshti Ave., Rasht, Guilan, IRAN

City

Rasht

Province

Guilan

Postal code

41469-39841

Phone

+98 13 3355 5058

Fax

+98 13 3355 0097

Email

zahra_taheri@gums.ac.ir

Web page address

http://www.gums.ac.ir/nmr

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available