# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 2026

## Developing, implementing, and evaluating a flipped classroom teaching method on CPR competency among medical emergency students

## Protocol summary

**Study aim**

1. To develop and validate a blended learning intervention 2. To implement the blended learning intervention in addition to traditional learning. Within the Research Question 1, the following further questions will be examined: To determine the effectiveness of the blended learning intervention, in addition to the traditional learning on CPR competency، CPR knowledge، CPR clinical skills، CPR clinical performance, satisfaction, critical thinking, and self-efficacy of medical emergency students across the study period.

**Design**

A single-center, parallel group randomized control trial design with balanced randomization (1:1) will be conducted

**Settings and conduct**

This study will be conducted in the Department of Emergency Medical Sciences, Faculty of Paramedical Sciences, Kurdistan University of Medical Sciences, Sanandaj, Iran

**Participants/Inclusion and exclusion criteria**

People were chosen to participate in this study if they: • Are Iranian • Being the undergraduate medical emergency student • Being able to access the online learning environment • Passed first aid or CPR exam. People were excluded from the study if they: • Unwilling to participate in this study • Being unable or unwilling to access online resources • Being first-year students

**Intervention groups**

The intervention group will receive the blended CPR training and the control group will receive the traditional CPR training

**Main outcome variables**

• CPR competency • CPR Knowledge • CPR Skills • CPR Performance • Satisfaction • Critical thinking • Self-efficacy

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160625028627N2**
Registration date: **2023-05-26, 1402/03/05**
Registration timing: **prospective**

Last update: **2023-05-26, 1402/03/05**
Update count: **0**

**Registration date**

2023-05-26, 1402/03/05

**Registrant information**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-10-23, 1402/08/01

**Expected recruitment end date**

2024-01-21, 1402/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Developing, implementing, and evaluating a flipped classroom teaching method on CPR competency among medical emergency students

**Public title**
CPR Competency: Developing, implementing, and evaluating a flipped classroom teaching method

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
People were chosen to participate in this study if they are Iranian Being the undergraduate Medical Emergency students admitted to the Department of Emergency Medical Sciences, Faculty of Paramedical Sciences, Kurdistan University of Medical Sciences, Sanandaj, Iran Being able to access the online learning environment Passed first aid or CPR exam

**Exclusion criteria:**
Unwilling to participate in this study Being unable or unwilling to access online resources Being first year students

**Age**
From **18 years** old

**Gender**
Both

**Phase**
0

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **102**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
A single-center, parallel-group randomized control trial design with balanced randomization (1:1) will be conducted. The aim of the study is to develop, implement and evaluate the effect of blended learning on the CPR competency of medical emergency students, using the competency outcomes and performance assessment (COPA) model. This study will be conducted in the Department of Emergency Medical Sciences, Faculty of Paramedical Sciences, Kurdistan University of Medical Sciences, Sanandaj, Iran. All undergraduate medical emergency students (the year 2023-2024) who are admitted to the Department of Emergency Medical Sciences will be invited to participate in this study. Randomization will be generated by permuted block randomization with allocation concealment. Participants will be divided into intervention or control groups. The intervention group will be exposed to the blended learning classroom The control group will be exposed to the traditional lecture classroom. Eligible participants will be randomized sequentially at the time they provided baseline assessment. Afterward, eligible patients will randomly be assigned to one of two treatment groups using blocked randomization by a computer-generated table of random numbers, a block size of four, and an allocation ratio of 1:1. Participants will be sequentially allocated to the study groups in the order in which they were recruited. Intervention assignment will be ascertained using sealed, opaque envelopes with consecutive numbering. The investigator who opens the envelopes and carries out the implementation of assignments will not be involved in the generation and allocation concealment.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Due to the nature of the intervention, neither participants nor lecturers can be blinded. A two-arm parallel-group randomized controlled trial with blinded outcome assessors and the data analyzer will be designed.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Kurdistan University of Medical Sceicnes ethic committee

**Street address**
Pasdaran Boulevard, Kurdistan University of Medical Sciences, Sanandaj, Iran

**City**
Sanandaj

**Province**
Kurdistan

**Postal code**
1344666179

**Approval date**
2023-05-20, 1402/02/30

**Ethics committee reference number**
IR.MUK.REC.1402.051

## Health conditions studied

### 1

**Description of health condition studied**
CPR Competency

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

CPR competency

**Timepoint**

Study outcomes will be measured at baseline, 8 and 12 weeks post intervention

**Method of measurement**

Professional Competency (MINI-CEX) It is a method of evaluation to assess the clinical skills of students through direct observation and provide constructive feedback. The mini-CEX checklist consists of 40 items with seven components area has been scored between 1 up 9 in each question of skills 'parts (in which 1–3 was “unsatisfactory,” 4–6 were “satisfactory,” and 7–9 were “above expected”), with a total score from 40 to 360. A higher score means the higher professional competency of nursing students. The seven different skill competency parts for evaluation of the student's professional skill competency such as; Nursing communication skills and history taking, physical examination skills, Nursing professionalism, Nursing intervention &clinical judgment, capabilities to provide Consultation / Health Education to patients and family, organization/efficacy, general nursing clinical competency.

## Secondary outcomes

### 1

**Description**

CPR Knowledge

**Timepoint**

The study outcome will be measured at baseline, 8 and 12 weeks after intervention

**Method of measurement**

A 10-item, multiple-choice questionnaire for the evaluation of theoretical knowledge will be used. The examiner will rate the participants’ actions based on the sequence of steps on the 10-item checklist for practical evaluation. Points will be given for actions performed correctly in sequence, and for the effectiveness and quality of chest compressions. Higher scores indicate better knowledge.

### 2

**Description**

CPR Clinical Skills

**Timepoint**

The study outcome will be measured at baseline, 8 and 12 weeks after intervention

**Method of measurement**

The skill test will be rated based on a checklist representing the performance guidelines set by the American Heart Association using low-fidelity human simulation. The tests for CPR skills will be completed by the researchers, who observed the students individually. All students will be evaluated on the same mock code situation for the skill test. The possible range of scores for each test was 0 to 25. Each student received 1 point for each of the skills they performed correctly and in the correct order; no points were granted for not performing the skill, performing in the incorrect order, or performing incorrectly.

### 3

**Description**

Clinical Performance

**Timepoint**

The study outcome will be measured at baseline, 8 and 12 weeks after intervention

**Method of measurement**

A 20-item checklist for the evaluation of practical performance will be used. Participants will be reassessed individually for their practical performance by examiners, blinded to group assignment, and rate the participants’ actions on a 20-min simulated scenario of cardiac arrest using a CPR training manikin. The checklist rating form is comprised of 20 items in three categories: leadership, teamwork, and team member skills. The checklist rating scores range from 1 to 5 for each item. A score of 1 is the lowest score and a score of 5 is the highest score. The leadership category consists of four subcategories: (1) organization, which means the ability to designate roles to team members such as chest compression, oxygen delivery, defibrillation, intravenous (IV) medication, and recording; (2) order giving, which represented the ability to give orders to team members, communicating the necessary timing and sequence of their actions; (3) support, characterized by the ability to aid team members in their various roles; (4) awareness, which describe the ability to perceive the situation and understand what actions must be taken. The teamwork category consists of six subcategories: (1) communication, which means the ability to effectively communicate with and deliver clear, concise messages to teammates; (2) cooperation, represented by the ability to cohesively work with teammates to achieve a common goal using patience, understanding and respect; (3) experience-sharing, characterized by the ability to share the simulation experience with fellow teammates; (4) ordering, which described the ability to effectively give orders to teammates; (5) Advanced Cardio-pulmonary Life Support (ACLS) principle adherence, which meant the ability to follow ACLS guidelines and protocols; and (6) task completion, signified by the ability to successfully complete the simulation. The team member category consisted of 10 subcategories: (1) patient contact, which meant the ability to make initial contact with the patient to determine consciousness and state of mind; (2) chest compression, which represented the ability to perform effective chest compressions on a patient; (3) airway check, characterized by the ability to check patient’s airways for obstructions; (4) oxygen delivery, which described the ability to consistently deliver oxygen to the patient using a bag valve mask; (5) defibrillation, which meant the ability to set up and use a defibrillator; (6) intubation, represented by the ability to efficiently and successfully intubate the patient; (7) IV medication, signified by the ability to inject appropriate medication through the patient’s IV; (8) monitoring, which represented the ability to monitor patient’s vital signs; (9) ECG recognition, characterized by the ability to monitor and understand patient ECG outputs; and (10) recording, which meant the ability to accurately record events of the simulation, including times for each of the

protocol steps, and procedures or medications used.

### 4

**Description**

Self-efficacy

**Timepoint**

The study outcome will be measured at baseline, 8 and 12 weeks after intervention

**Method of measurement**

The resuscitation self-efficacy scale was selected to measure the participant's self-efficacy. Resuscitation self-efficacy is defined as a judgment of the perceived capability to organize and execute the process of care during resuscitation. Read each statement and then select the response that best indicates your level of agreement. This scale included 17 items with a four-component structure termed ‘Recognition’, ‘Debriefing and recording’, ‘Responding and rescuing’, and ‘Reporting’. The Resuscitation Self-Efficacy Scale for nurses yields reliable and valid results in appraising the level of resuscitation self-efficacy for Korean nurses. Each subscale and the total scale demonstrated satisfactory internal consistency: 0.82; 0.88; 0.87; 0.83; and 0.91 respectively.

### 5

**Description**

Critical thinking skills

**Timepoint**

The study outcome will be measured at baseline, 8 and 12 weeks after intervention

**Method of measurement**

The researcher used an assessment tool (35 items) developed to measure problem-solving and decision-making skills in nursing students after obtaining permission from the author (Yoon, 2004). This tool is a composite of 8 factors. The factors were identified as ‘intellectual integrity(6 items)’, ‘creativity(4 items)’, ‘challenge(6 items)’, ‘open-mindedness(3 items)’, ‘prudence(4 items)’, ‘objectivity(4 items)’, ‘truth seeking(3 items)’ and ‘inquisitiveness(5 items)’. The reliability of the scale, Cronbach's alpha was .892 and the factors' ranged from 0.562-0.836.

### 6

**Description**

Satisfaction

**Timepoint**

The study outcome will be measured at baseline, 8 and 12 weeks after intervention

**Method of measurement**

student confidence and satisfaction with the teaching method questionnaire were used in this study. This questionnaire consists of 7 questions. This questionnaire includes questions such as (1) an assessment of confidence in performing CPR, (2) an assessment of the appropriateness of the length of the training course, (3) satisfaction with the teaching method, (4) satisfaction with the length of the training course, (5) satisfaction with the number Exercise frequency, (6) Assessing student performance in emergencies, (7) How to improve the quality of teaching. Each question will be analyzed separately and the results will be reported qualitatively. This questionnaire has never been validated in Iran. Before implementing the instrument, we will translate this questionnaire and check its validity and reliability.

## Intervention groups

### 1

**Description**

Intervention group: Blended learning CPR education: The blended learning CPR education program is designed as an eight-session program. • In Session 1, program orientation, will be given. • In Session 2, students will watch videos containing information about heart rhythm, and heart arrhythmia. • In Session 3, students will watch a video titled “How to perform chest compression CPR and use the automated defibrillator.” The video described the definition of CPR, the overall CPR process, the basics of chest compression CPR, and how to use an automated defibrillator. • In Session 4, students will watch a video titled “Basic course for standard CPR education program”. The video contained information about cardiac arrest cases and the need for CPR, successful CPR cases, the chest compression process, chest compression training, cases in which no one is available to help, repeated CPR training, how to use an automated defibrillator, precautions for using a defibrillator, how to use cardioversion, and how to deliver rescue breaths. • In Session 5, students will watch videos containing information about rapid ACLS algorithm review. • In Session 6, students will be encouraged to observe the CPR simulation in the skill lab using the Nursing Department Simulation Centre on campus which is equipped with SimMan Laerdal high-fidelity mannequins. • In Session 7, Students will be randomly placed into small groups to maximize hands-on time in the simulation center. Each group will be scheduled to have 1 day in the simulation center. Within each group, students will be paired, and each pair participated in 1 simulation scenario that required the use of CPR and observing their peers in other scenarios on the day of their scheduled simulation. The peer observer will be in the same room as the pair participating in the simulation and will be able to see and hear all actions taking place in the scenario. However, the peer observers will be given strict instruction by the investigators to not speak, assist the participating pair, or intervene in the simulation in any way. Materials will include, but will not be limited to, an automated external defibrillator, stethoscope, CPR mask, tape and bandage materials, and gloves. During the simulation scenario, neither student will be assigned the lead role in assessing the victim or responding to the scenario. The investigators purposefully will not assign roles to the participating pair and unfollow the participants to fully experience their communication and teamwork abilities. Within each simulation scenario, the students will be required to initiate an assessment, activate the Emergency Medical System (EMS), perform CPR, use an automated external

defibrillator and other emergencies medical equipment, and reports paramedics responding to the call. The role of the EMS paramedics responding to the call will be played by 2 senior-level athletic training students. •In Session 8, students will be given a lecture using a printout made by the investigator based on the key contents of the KACPR guideline and 2010 AHA guideline for CPR and emergency cardiovascular treatment. Teaching – Learning methods: Blended learning (online resources and classroom discussion)Discussion – critical thinking Role playing and case study reviews Assignments Activities/ExercisesTeaching aids: is developed by the educators and instructors video presentationWhiteboard Handout Scenarios/simulation Computer and LCD, and e-learning system in Kurdistan University of medical sciences.

**Category**

Other

**2**

**Description**

Control group: Participants in this group will receive traditional CPR training based on the critical care medical emergency curriculum designed by the Iranian Ministry of Health for medical emergency undergraduate students. This course is a three-credit theory course. This course requires learners to pass internal emergencies 1-3 as specific prerequisites. The curriculum Is divided into two sections: Section 1: Cardiac arrhythmias diagnosis and treatment of cardiac arrhythmias, and providing comprehensive emergency care in patients with arrhythmias. The ultimate goal of antiarrhythmic drug therapy, Assessing Changes in a Patient's Condition, and identify the medical emergency technician roles that contribute to better outcomes, drug classification of cardiac arrhythmias including Bradyarrhythmias, tachyarrhythmia, supraventricular arrhythmias, and ventricular arrhythmias. Overview of atrioventricular blocks and changes in conduction, and medical emergency intervention and rehabilitation activities to improve wellbeing with cardiac dysrhythmias. Section 2: cardiopulmonary resuscitation: An overview of arterial fibrillation, Asystole clinical presentation, Principles of CPR cardiopulmonary resuscitation (basic and advanced life support) with the aim of applying emergency care and ethical code consideration. Teaching – Learning methods: Face-to-face lecturing and presentation, Discussion – critical thinking Role playing and case study reviews Assignments Activities/ExercisesTeaching aids developed by the educators and instructors, Whiteboard, Handout, Scenarios/simulation Computer, and LCD.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Department of Emergency Medical Sciences, Faculty of Paramedical Sciences, Kurdistan University of M

**Full name of responsible person**

Golnaz Azami

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## Sponsors / Funding sources

**1**

**Sponsor**

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**Grant name**

IR.MUK.REC.1402.051

**Grant code / Reference number**

IR.MUK.REC.1402.051

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

Yes

**Title of funding source**

Sanandaj 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**
Sanandaj University of Medical Sciences

**Full name of responsible person**
Golnaz Azami

**Position**
Nurse

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nursery

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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**
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**
Not applicable

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

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
The study findings will be published in a scientific journal. The participants' information dataset, study protocol, statistical analysis map, and participant's written consent form will be available upon request.

**When the data will become available and for how long**
The year 2024

**To whom data/document is available**
Journal editors, Journal reviewers, and readers who are eager to receive more information about the study

**Under which criteria data/document could be used**
Journal reviewers/editors and those readers who are eager to receive more information about the study will receive the study information. Maintaining the confidentiality and anonymity of participants' information is essential for accessing the research data.

**From where data/document is obtainable**
Send a request to access datasets using the following email: golnaz azami64@gmail.com

**What processes are involved for a request to access data/document**
A data availability statement will be signed by the person who wants to access the study information. Upon signature of the statement, the dataset will be shared

within 24 hours.

**Comments**