# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparing the effects of two methods of smartphone-based software and role-playing for teaching neonatal resuscitation program on self-efficacy, knowledge and clinical skills of undergraduate nursing students

## Protocol summary

**Study aim**
Impact of Smartphone Software and Role-Playing on Self-Efficacy, Knowledge, and Clinical Skills in Neonatal Resuscitation Among Undergraduate Nursing Students at Shiraz University of Medical Sciences. in 2025-2026

**Design**
A cluster randomized trial with a control group and two intervention groups, double-blind, phase 3 on 112 undergraduate nursing students.

**Settings and conduct**
The research will be conducted at the Faculty of Nursing and Midwifery of Hazrat Fatemeh in Shiraz. During the second semester of the 2024-2025 academic year and the first semester of the 2025-2026 academic year, the researcher will visit classes of 7th and 8th-semester nursing students. Written informed consent will be obtained from students who are interested in participating after the research purpose is explained.

**Participants/Inclusion and exclusion criteria**
1. Having an Android phone 2. Willingness to participate in the study

**Intervention groups**
Smartphone-based software intervention group: For the smartphone-based software test group, the neonatal resuscitation program training will be installed on Android. Role-playing intervention group: the students in the role-playing intervention group will be presented with a resuscitation scenario. Control Group: students in the control group will only receive the standard neonatal resuscitation program training in the form of lectures using PowerPoint and video presentations.

**Main outcome variables**
Self-efficacy, clinical knowledge and skills

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250421065433N1**
Registration date: **2025-05-13, 1404/02/23**
Registration timing: **prospective**

Last update: **2025-05-13, 1404/02/23**
Update count: **0**

**Registration date**
2025-05-13, 1404/02/23

**Registrant information**

**Name**
fateme eshghi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 917 846 7420

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-09-23, 1404/07/01

**Expected recruitment end date**
2026-03-06, 1404/12/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparing the effects of two methods of smartphone-

based software and role-playing for teaching neonatal resuscitation program on self-efficacy, knowledge and clinical skills of undergraduate nursing students

**Public title**
The effect of two methods: smartphone-based software and role-playing for teaching neonatal resuscitation program on self-efficacy, knowledge, and clinical skills of undergraduate nursing students
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having an Android phone Willingness to participate in the study
**Exclusion criteria:**
Participate in another neonatal resuscitation program educational study during the duration of this research.
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **112**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Eligible samples will be placed into intervention and control groups using cluster randomization.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, participants, as well as data collectors and data analysts, will be kept blind to the study groups.
**Placebo**
Not used
**Assignment**
Other
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Shiraz University of Medical Sciences
**Street address**
Opposite Palestine Street, Zand Street, Shiraz
**City**
Shiraz
**Province**
Fars
**Postal code**
71348-14336
**Approval date**
2025-02-05, 1403/11/17
**Ethics committee reference number**
IR.SUMS.REC.1403.483

## Health conditions studied

### 1

**Description of health condition studied**
Undergraduate Nursing Students
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Self-efficacy score
**Timepoint**
Before the intervention, after the intervention and one month later
**Method of measurement**
The Resuscitation Self-efficacy Scale will be used.

### 2

**Description**
Knowledge score
**Timepoint**
Before the intervention, after the intervention and one month later
**Method of measurement**
It will consist of 30 multiple choice questions (MCQs) based on the steps of the neonatal resuscitation program that will assess knowledge of neonatal resuscitation.

### 3

**Description**
Clinical skill score
**Timepoint**
Before the intervention, after the intervention and one month later
**Method of measurement**
The OSCE Neonatal Resuscitation Checklist and Neonatal Resuscitation Scenario will be used to assess clinical skills.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Smartphone-based software for the test group Smartphone-based software, training in the neonatal resuscitation program under Android, will be installed. This software will be available to the test group for one month and will be locked after one month. The educational software will be installed on the students' phones in a one-hour session and they will be trained on how to use it. Web programmer engineers and graphic designers will be used to design the background and icons to prepare the educational software. The content of the educational program will be created based on the 2021 American Heart Association guidelines, which will consist of 4 main sections: introducing the software, listing, introducing educational resources, and exiting the program. In order to prevent information contamination and the lack of access to the software by the role-playing and control intervention groups and other students until the end of the study, it will be foreseen for the software password that each virtual user who has a defined password for himself can use to log in and install the software. A management software will also be used to track the number of times the software is logged in, which will display the usage of each user. For the scientific validity of the software, the opinions of 3 faculty members who are experts in the fields of neonatal intensive care, neonatal resuscitation program, and smartphone-based software design will be used. After collecting expert opinions, the necessary corrections will be made.

**Category**

Other

**2**

**Description**

Intervention Group Role-Playing Intervention: After receiving the usual training using PowerPoint and film, the students in the role-playing intervention group will be presented with a resuscitation scenario. Based on the scenario, each student will be assigned a specific role in the resuscitation team, such as team leader, massage therapist, airway management, or medication administration. The students will then form groups of four and, under the supervision of a project partner (with a master's degree in neonatology and 12 years of experience in working and teaching in the field of neonatology), will actively participate in performing a real resuscitation scene and apply their knowledge and skills in a simulated real world.

**Category**

Other

**3**

**Description**

Control group: Students in the control group will only receive the standard neonatal resuscitation program training, which is delivered through lectures using PowerPoint and video presentations.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Hazrat Fatemeh School of Nursing and Midwifery, Shiraz

**Full name of responsible person**

Fateme Eshghi

**Street address**

Entrance to Namazi Hospital, Namazi Square, Shiraz

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Shiraz

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**Postal code**

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+98 71 3647 4254

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eshghifateme@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr-Hamid Mohammadi

**Street address**

Opposite Palestine Street, Zand Street, Shiraz

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mohammadi@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**
Fateme Eshghi
**Position**
Assistant professor
**Latest degree**
Ph.D.
**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)**
Undecided - It is not yet known if there will be 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**
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 protocol and scientific articles resulting from the research will be published in reputable journals.
**When the data will become available and for how long**
After publication
**To whom data/document is available**
All people interested in this field
**Under which criteria data/document could be used**
It can be used if intellectual property is preserved.
**From where data/document is obtainable**
Publisher's magazine website
**What processes are involved for a request to access data/document**
There is no specific process.
**Comments**