

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Email address

fatemeeshghi@sums.ac.ir

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

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶ - ۷۱۱۱۹

Phone

+98 71 3647 4254

Email

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

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

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

Street address

Entrance to Namazi Hospital, Namazi Square, Shiraz

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+98 71 3647 4254

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eshghifateme@yahoo.com

Person responsible for scientific 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 updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Eshghi

Position

Assistant Professor

Latest degree

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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