Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Designing, implementing and evaluating the Respiratory Critical Care Nurse Training Program: Multimethod Study

Protocol summary

Study aim

Design, implementation and evaluation of the respiratory intensive care nurse training program

Design

Randomized with controlled, parallel-group, triple-blind, , phase 2 clinical trial on 100 patients. RAS software was used for randomization.

Settings and conduct

A randomized controlled clinical superiority trial with triple blinding and a two-arm parallel group design will be conducted at Baqiyatallah University of Medical Sciences in Tehran, Iran The participants will consist of critically ill patients who will be randomly allocated in a 1:1 ratio into two groups: Patients, respiratory intensive care nurses, and the statistician will be blinded to ensure impartiality and minimize allocation bias.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of at least 18 years; Admitted to the intensive care unit; suffering one of the types of respiratory problems; willingness to participate in the study. Exclusion criteria: final stages of life; unwillingness to continue participation; history of neuromuscular diseases or cardiorespiratory arrest.

Intervention groups

Patients will be divided into two intervention or control groups based on random assignment according to the inclusion criteria. The intervention group will receive specialized respiratory care from respiratory care nurses from the time of admission to the intensive care unit until discharge from the intensive care unit, and the control group will receive only routine hospital care.

Main outcome variables

The primary outcome of this study will be a comparison of ICU-mortality rates between the two study groups. The secondary outcome will be the proportion of treatment failures, defined as a composite endpoint consisting of the need for non-invasive ventilation (NIV), intubation, or death at the time of ICU discharge.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241216064077N1**
Registration date: **2025-07-18, 1404/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-18, 1404/04/27**
Update count: **0**

Registration date

2025-07-18, 1404/04/27

Registrant information

Name

Malihe Salimi bani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2254 9001

Email address

malihsalimi93@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-19, 1404/02/29

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, implementing and evaluating the Respiratory Critical Care Nurse Training Program: Multimethod Study

Public title
Designing, implementing and evaluating the Respiratory Critical Care Nurse Training Program
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are critically ill and require admission to the ICU will be eligible for enrollment if they meet the following criteria: Age of at least 18 years old Critical care requirement due to their illness No history of heart disease, stroke, autoimmune disease, neuromuscular diseases, cancer, or cardiorespiratory arrest Willingness to participate in the study
Exclusion criteria:
Patients who are pregnant and breastfeeding Patients at end-stage medical condition, or patients with planned withdrawal of treatment
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Convenience sampling will be used to enroll participants in the study. Randomization will be performed using blocks of four using SAS software by a statistician not involved in the study. Blocked randomization is used to balance the number of samples allocated to each study group to ensure that exactly equal numbers of participants are assigned to the intervention and control groups at successive time intervals. Four people will be assigned to the intervention group and then four people will be assigned to the control group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The allocation consignment will be carried out by the hospital clinical supervisor, who is not involved in the participant recruitment. Patients, RCCNs, and data analysts will be blinded to the allocation to ensure impartiality and minimize bias.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Mulla Sadra Ave
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2024-10-20, 1403/07/29
Ethics committee reference number
IR.BMSU.BAQ.REC.1403.161

Health conditions studied

1

Description of health condition studied
Unstable vital condition
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
ICU-mortality rates
Timepoint
Before the study, during the study, one month after the intervention
Method of measurement
Electronic health system, intensive care unit documentation, death certificate

Secondary outcomes

1

Description
Need for invasive or non-invasive ventilation
Timepoint
72 hours after the intervention
Method of measurement
observation/Yes or No

2

Description

Readmission

Timepoint

72 hours after discharge from the intensive care unit

Method of measurement

Yes or NO

Intervention groups

1

Description

Intervention group: All critically ill patients who meet the inclusion criteria (as mentioned in the trial population section) and referred to the Baqiyatallah Hospital ED will receive routine medical care. However, they will be assigned to either the intervention or control group based on random allocation. Patients in the intervention group will receive RCCNs support from admission to the ED until discharge from the hospital. Critical care nurses, whose job descriptions were determined after completing the research stages of a scoping study, contractual content analysis, and three Delphi rounds, manage all of the patient's respiratory needs and problems, including oxygen therapy, intubation if necessary, suction and respiratory physiotherapy, lung function testing, and ventilator settings. The RCCNs will manage all respiratory needs and problems, accompany patients during transfers from the ED to the ICU and general wards, and provide ongoing support.

Category

Treatment - Other

2

Description

Control group: Patients in the control group will only receive routine medical care and will not receive RCCNs support.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Malihe salimi

Street address

Baqiyatallah hospital, Mulla Sadra Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Abbas Ali Emani Folladi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Malihe Salimi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Amir Vahedian Azimi

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Professor

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Nursery

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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
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