Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Designing and evaluating the impact of the "Simplified Tracheostomy Care Package" on the self-efficacy and performance of nurses working in intensive care units

Protocol summary

Study aim

Designing and developing a simplified tracheostomy care package based on valid scientific evidence and evaluating its impact on the self-efficacy and performance of nurses working in intensive care unit

Design

The trial will be conducted with blinding and randomization. In phase one, the package design will be carried out. In phase 2, 70 nurses working in intensive care units will be divided into two groups: experimental and control. The randomization function of Excel software will be used for randomization. The intervention will be carried out. Then, the effect of the package will be evaluated.

Settings and conduct

In the first phase, the design of the care package was carried out, and in the second phase, the package will be evaluated on nurses working in intensive care units. The study will be conducted at Shahid Sadoughi and Rahnemoon hospitals in Yazd.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Resources that directly address tracheostomy care in adults. • Expert panel: 1. Be a member of the university faculty. In the second stage: 1. Be nurses working in the intensive care units of Shahid Sadoughi and Shahid Rahnemoon hospitals in Yazd. Exclusion criteria: In the first stage (closed design): 1. Be related to the pediatric or neonatal population. In the second stage (clinical intervention): 1. Nurses who are on leave at the time of implementation of the intervention.

Intervention groups

The intervention for the experimental group will be: • a) Face-to-face training • b) Providing reminder tools • c) Immediate feedback The control group will not receive any study-related educational intervention during this period.

Main outcome variables

The outcome of the intervention will be assessed on the self-efficacy and performance of nurses working in Shahid Sadoughi and Shahid Rahnemoon hospitals in Yazd in tracheostomy care.

General information

Reason for update

Increasing the number of sampling environments

Acronym

IRCT registration information

IRCT registration number: **IRCT20260226068953N1**
Registration date: **2026-05-17, 1405/02/27**
Registration timing: **prospective**

Last update: **2026-06-23, 1405/04/02**
Update count: **1**

Registration date

2026-05-17, 1405/02/27

Registrant information

Name

Amir Farsiou

Name of organization / entity

Islamic Azad University of Yazd

Country

Iran (Islamic Republic of)

Phone

+98 41 3545 0897

Email address

amir.farsiou1395@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Designing and evaluating the impact of the "Simplified Tracheostomy Care Package" on the self-efficacy and performance of nurses working in intensive care units

Public title
Designing and evaluating the impact of the "Simplified Tracheostomy Care Package" on the self-efficacy and performance of nurses working in intensive care units

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
In the first stage (closed design): Textual sources and documents that directly address tracheostomy care in adults in special wards are included in the study. They should be clinical guidelines, standard protocols, or original articles/systematic reviews with a high level of evidence. Published in Persian or English within the last 5 years (2020 to 2025). Their full text is available. Expert Panel: Specialists who: have a PhD or Master's degree in nursing (specialization) or specialization in anesthesia or critical care will be included in the study. Be a member of the university faculty or have a relevant clinical or educational position. Have at least 5 years of useful work experience in intensive care and tracheostomy departments. Willingness to participate and sufficient time to review and rate items. In the second stage (clinical intervention): Nurses who work in the intensive care units of Shahid Sadoughi and Shahid Rahnemoon hospitals in Yazd will be included in the study. Have a bachelor's degree in nursing or higher. Have at least 6 months of clinical work experience in the intensive care unit. Have written informed consent to participate in the research.

Exclusion criteria:
Nurses who are on leave. Nurses who are unwilling to participate in the study.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, all eligible nurses in the intensive care units of Shahid Sadoughi and Shahid Rahnemoon hospitals in Yazd are listed by census method. From among the listed individuals, 70 individuals are selected by simple random method (using a table of random numbers or lottery). Then, these 70 individuals are divided into two groups: test (intervention) and control by random assignment method.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blinding will be done in a three-way blind manner. In this way, the participants, researcher, and data analyst will not be aware of the coding and banner division of the control and experimental groups. This means that the nurses will not be aware of the allocation to the control and experimental groups.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
research Ethics committees of islamic azad University - isfahan (khorasgan) branch

Street address
Islamic Azad University of Isfahan Branch (Khorasgan)، Daneshgah Blvd، Arghavanieh، East Jay St. ، Isfahan

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Khorasgan

Province
Isfehan

Postal code
8155139998

Approval date
2026-04-12, 1405/01/23

Ethics committee reference number
IR.IAU.KHUISF.REC.1405.016

Health conditions studied

1

Description of health condition studied
Tracheostomy care

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Self-efficacy of nurses
Timepoint
Beginning of the study, two weeks after the end of the intervention
Method of measurement
The self-efficacy scale will be the confidence level questionnaire that was used in the study of Onovah's PhD and in the study of Fatema Abdoltaeb.

2

Description
Performance of nurses
Timepoint
Beginning of the study, two weeks after the end of the intervention
Method of measurement
Tracheostomy Care Questionnaire: To assess the performance of nurses, the Tracheostomy Care Questionnaire will be used. This questionnaire was designed by Kashaninia et al. (8) and was derived from the study by Moussazadeh et al. (28).

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Control group: The intervention is implemented only for the experimental group and includes the following multifaceted strategy:• a) Face-to-face training: Holding small workshops for 45 to 60 minutes in the ward conference room or nursing station. The workshop content includes a brief review of theoretical principles followed by practical exercises on a model or educational equipment based on the "5 Golden Steps of the Care Package".• b) Providing reminder tools:1. Pocket card: Distributing laminated cards in pocket size on which the 5 main actions of the package are printed.2. Wall poster: Installing a graphic and colored poster of the simplified care package algorithm above the heads of tracheostomy patients and in the dirty/clean workroom. C) Immediate feedback: In the first week after training, the researcher will be present in the ward, answer any possible questions, and provide corrective feedback.
Category
Other

2

Description
Control group: During this period, the control group only received routine ward care and did not receive any educational intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospitals in Yazd
Full name of responsible person
Amir farsiou
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Ibn Sina Boulevard، Shahid Ghandi Boulevard، Yazd، Yazd Province
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2

Recruitment center
Name of recruitment center
Shahid Rahnemoon Hospitals in Yazd
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Yazd Branch
Full name of responsible person
Amir farsiou

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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
Islamic Azad University, Yazd Branch

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
Islamic Azad University, Yazd Branch
Full name of responsible person
Amir farsiou
Position
Master's student in critical care nursing
Latest degree
Bachelor
Other areas of specialty/work
Surgical technologist
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be published publicly and confidentially to help advance education.

When the data will become available and for how long

After completing data analysis

To whom data/document is available

Researchers, investigators, and individuals involved in the clinical care of tracheostomy patients.

Under which criteria data/document could be used

In order to protect patient privacy and advance scientific insights

From where data/document is obtainable

To the journal that will publish the study results.

What processes are involved for a request to access data/document

The requester can access the data by obtaining permission from the researcher, protecting patient privacy, and by referring to journals.

Comments