Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of training on tracheotomy care using simulation and application methods on the anxiety and self-efficacy of the main caregivers of the patients admitted at home

Protocol summary

Study aim
Comparison of the effect of tracheostomy care training with simulation and application methods on anxiety and self-efficacy of primary caregivers of hospitalized patients at home

Design
Randomized clinical trial

Settings and conduct
The present study is a clinical trial. The study population included the main cargivers of patients admitted to intensive care units of hospitals affiliated to Tehran University of Medical Sciences, who were discharged by mechanical ventilation.

Participants/Inclusion and exclusion criteria
>60 years Having an Android phone by someone close to the patient who is taking care of him Ability to write and read Willingness to participate in the study First discharge with tracheostomy Ability to understand and speak Persian No hearing, touch, visual and speech disorders

Intervention groups
Intervention group 1: simulation in clinical setting
Intervention group 2: training via application

Main outcome variables
Anxiety Self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111203008286N7**
Registration date: **2019-10-14, 1398/07/22**
Registration timing: **prospective**

Last update: **2019-10-14, 1398/07/22**
Update count: **0**

Registration date
2019-10-14, 1398/07/22

Registrant information

Name
Fatemeh Bahramnezhad

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-20, 1398/08/29

Expected recruitment end date
2020-11-19, 1399/08/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of training on tracheotomy care using simulation and application methods on the anxiety and self-efficacy of the main caregivers of the patients admitted at home

Public title
training on tracheotomy care u

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

<65 years Having an Android phone by someone close to the patient who is taking care of him Ability to write and read First discharge with tracheostomy Willingness to participate in the study No hearing, touch, visual and speech disorders Ability to understand and speak Persian

Exclusion criteria:

The participnt's unwillingness to continue participating in the study

Age

To **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Research samples (main caregiver) with inclusion criteria will be divided into three groups using blocking method. There are 9 possible ways to equally assign participants to block. Allocation proceeds by randomly selection by randomization.com and after that participants enter the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery and Rehabilitation, Tehran University of Medical Sciences

Street address

School of Nursing and Midwifery, Tohid Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.TUMS.FNM.REC.1398.083

Health conditions studied

1

Description of health condition studied

Anxiety and self-efficacy of the main caregiver

ICD-10 code

J95.85

ICD-10 code description

Complication of respirator [ventilator]

Primary outcomes

1

Description

Anxiety: In this study, anxiety of caregivers of patients with tracheostomy will be measured one month after intervention.

Timepoint

One month after intervention

Method of measurement

Hamilton Anxiety Rating Scale (HAM-A)questioner

2

Description

Self-efficacy: In this study, self-efficacy of caregivers of patients with tracheostomy will be measured one month after intervention.

Timepoint

One month after intervention

Method of measurement

Caregiver Inventory(CGI)questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After getting informed consent, anxiety and self-efficacy questionnaires will be given to the samples and then the application will be installed on their mobile phones and their levels of anxiety and self-efficacy will be measured a month later .

Category

Behavior

2

Description

Intervention group2:After getting informed consent, the anxiety and self-efficacy questionnaires were given to the samples, and exactly the same educational content as trained for the application group, in three 15-minute sessions and in the final three days before discharge to

the hospital in the center. The clinical skills training of the Tehran School of Nursing and Midwifery will be taught to the patient's primary caregiver. Then, one month after clearing their anxiety levels and self-efficacy will be measured.

Category

Behavior

3

Description

Control group: At first, informed consent forms, anxiety and self-efficacy questionnaires will be completed, will receive routine care, and will be completed one month after the anxiety and self-efficacy questionnaire is discharged. After studying the educational content they will be provided

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomini Hospital

Full name of responsible person

Fatemeh Bahramnezhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

DR. Sahraian

Street address

Tehran University of Medical Sciences, Keshavarz Blv. Tehran, Iran

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144567889

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Bahramnezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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