

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 caregivers 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

fatemeh_bahramnezhad@yahoo.com

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 participant'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**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

Street address

School of Nursing and Midwifery, Tohid Sq., Tehran, IRan

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4416

Email

bahramnezhad.f@gmail.com

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

City

Tehran

Province

Tehran

Postal code

144567889

Phone

+98 21 8163 3698

Email

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

Street address

School of Nursing and Midwifery, Tohid Sq.,Tehran, IRan

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4416

Email

bahramnezhad.f@gmail.com

Person responsible for scientific 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
Street address
School of Nursing and Midwifery, Tohid Sq., Tehran,
Iran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4146
Email
bahramnezhad.f@gmail.com

Person responsible for updating data

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
Street address
School of Nursing and Midwifery, Tohid Sq., Tehran,
Iran
City

Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4416
Email
bahramnezhad.f@gmail.com

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