

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of family centered education in invasive home mechanical ventilation patients

Protocol summary

Study aim

Determining of the effect of family-centered education on the level of performance and family burden at home

Design

Clinical trial, intervention and control group, randomized, single center, Sampling type: available eligibles, Segmentation: Random blocks with quadruple blocks

Settings and conduct

Place of study: Tehran University of Medical Sciences and Health Services

Participants/Inclusion and exclusion criteria

Inclusion criteria: Desire for participating in the study
The patient is under invasive home mechanical ventilation The primary caregiver is the person who has the most involvement in the treatment The caregiver should be able to read and write at least
Exclusion criteria: In case of participation in a study that interferes with the current study

Intervention groups

Intervention group: After obtaining informed consent and the completion of the researcher-made checklists, Home care training (routine and emergency) is given to the family in 5 sessions of 1 hour in 4 weeks.. Control group: After obtaining informed consent and the completion of the researcher-made checklists, They will receive routine intensive care training.

Main outcome variables

Family performance level, Family burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210205050252N1**

Registration date: **2021-03-04, 1399/12/14**

Registration timing: **prospective**

Last update: **2021-03-04, 1399/12/14**

Update count: **0**

Registration date

2021-03-04, 1399/12/14

Registrant information

Name

پروانه Asgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6524 8931

Email address

p-asgari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family centered education in invasive home mechanical ventilation patients

Public title

Effect of family education at home

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Desire for participating in the study The patient is under

invasive home mechanical ventilation The primary caregiver is the person who has the most involvement in the treatment The caregiver should be able to read and write at least

Exclusion criteria:
In case of participation in a study that interferes with the current study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The sequence of random allocation and the list of blocks will be obtained by the statistical consultant with the help of software. The website <http://www.sealedenvelope.com> is a useful site for generating random sequences for block type randomization. This site is designed in such a way that there is no limit on the number of groups for random allocation. Volume block method four is used to create random allocation sequences. Blocks consisting of two groups A and B randomly selected using the software such as (BAAB) , (ABBA) , (AABB) , (BBAB). Then 60 pockets (30 pockets containing paper A and 30 pockets containing paper B) will be prepared based on sample size. According to a list of blocks, a trained person outside of the research team will be set the row of pockets. In the first stage, each patient will be randomly assigned to the A group (intervention) or B group (control). The sample process will be performed sequentially until the end of completion of sample size. Code of each patient will also be allocated to his family member. Patients are assigned to the study group in order of their entry into the study and randomly through randomized blocks. For example, according to the block (ABAB), each patient enters the intervention, control, intervention and control groups, respectively, after entering the study. This process continues until the last block is selected.

Blinding (investigator's opinion)
Double blinded

Blinding description
The assignment of the groups will be done by someone out of the study and the investigator won't have any information about the assigned group. The group code of individuals will only be available to the lead researcher (supervisor) and the evaluators will not be aware of it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Nursing and Midwifery and School of Rehabilitation, Tehran University

Street address

Nursing & Midwifery School, East Nosrat st., Tohid sq

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.TUMS.FNM.REC.1398.114

Health conditions studied

1

Description of health condition studied

Performance skills and family burden

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Performance skills score in researcher-made checklists

Timepoint

Before and one week after education

Method of measurement

Researcher-made functional skills checklist

Secondary outcomes

1

Description

Family burden score

Timepoint

Three month after the intervention

Method of measurement

ZARIT burden questionnaire

Intervention groups

1

Description

After getting informed consent, the main family caregiver will receive routine and emergency care training including suction, gavage, skin care, and cardiopulmonary resuscitation via face to face and on a replica before the patient is discharged home. The duration of the training will be five one-hour training sessions. The mentioned training booklet will also be provided to the family.

Category

N/A

2

Description

In the control group, the main family member will receive routine intensive care unit training including suction, gavage and skin care in a brief training session during discharge.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Parvaneh Asgari

Street address

Nursing & Midwifery School, East Nosrat st., Tohid sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Deputy of research and technology, Sixth floor,
Central organization of university, Corner of Quds St,
Keshavarz Blvd

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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

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

Parvaneh Asgari

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Nursery

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

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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

Not applicable

Data Dictionary

Not applicable