

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of using communication board on physiological parameters and perceived quality of care in patients with artificial airways

Protocol summary

Study aim

Determining the effect of communication board on physiological parameters and perceived quality of nursing care in patients with artificial airway.

Design

A randomized study with control group, parallel groups, without blinding, without placebo, randomization with blocking method with 60 samples

Settings and conduct

The research environment will be critical care units. Firstly, a demographic questionnaire will be completed. Blood samples were then collected between 7 and 8 am in both groups to assess cortisol levels. Vital signs will also be recorded in both groups. In the intervention group, the communication board is provided in the morning shift. In the control group, the nurse-patient communication method will be routine, by the nurse, and the patient will answer non-verbally. A second blood sample will be collected from both groups at 10:30 am to 11:30 am and vital signs of both groups will be recorded. Then nursing care quality questionnaire will be completed in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 60, having artificial airway, full consciousness and no use of sedative drugs, minimum literacy, speaking and understanding Persia, no hearing or sight or cognitive problems, no history of having artificial airway, no use of drugs effecting cortisol level, no disease and medications that affect hemodynamic parameters. exclusion criteria: psychotic and depressive disorder, definitive or probable diagnosis of brain injury, and no Willingness to participate in research.

Intervention groups

In the intervention group, the communication board is given to the patient in the morning shift to communicate. In the control group, the nurse-patient communication method will be routine, like nurse's frequent questions and patient's non-verbally responses

Main outcome variables

Serum cortisol level, vital signs, quality of nursing care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190914044768N1**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

anahita divani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6617 9056

Email address

adivani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using communication board on physiological parameters and perceived quality of care in patients with artificial airways

Public title

The effect of communication board on physiological parameters and quality of nursing care

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 60 years old having oral/nasal endotracheal tube or tracheostomy Complete consciousness (GCS = 9 + T, 10+T and four score = 13) not receiving sedative medications Minimum literacy Speech and understanding of Persian language Lack of hearing, visual or cognitive impairment No previous intubation or previous tracheostomy Not taking medications that affect cortisol level No disease affecting hemodynamic parameters. Not taking medications that affect hemodynamic parameters

Exclusion criteria:

The definitive or probable diagnosis of brain injury Unwillingness to participate in research Psychotic diseases and depression

AgeFrom **18 years** old to **60 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

Because there is no list of patients, there is no information contamination. Therefore, the blocking method is used for randomization. Thus, letter A is considered as intervention group and letter B is considered as control group. Then write all the permutations of the letters A, A, B and B, which are 6 different combinations on the 6 cards: 1. AABB, 2. ABBA, 3. ABAB, 4. BAAB, 5. BABA, 6. BBAA, We then randomly select between 1 and 2 digits (using the random number table or asking patient number one to select a card randomly). For example, if the digit 1 is selected, it means that the first patient will be in the intervention group, the next two patients will be in the control group and the fourth patient will be in the intervention group.

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**

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

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Mirkhani sreet, Tohid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-09-07, 1398/06/16

Ethics committee reference number

IR.TUMS.FNM.REC.1398.108

Health conditions studied**1****Description of health condition studied**

using artificial airway

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

serum cortisol level

Timepoint

firstly, 7 to 8 am before intervention, after intervention 10:30 to 11:30 am

Method of measurement

3 ml blood sample through peripheral veins

2**Description**

vital signs

Timepoint

firstly before intervention 7 am, then after intervention 1 pm

Method of measurement

Vital Signs Monitoring Device

3

Description

perceived quality of nursing care in communication dimension

Timepoint

firstly before intervention 7 am, then after intervention 1 pm

Method of measurement

quality of nursing care questionnaire (QUALPAC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, at the beginning of the intervention, the cause and manner of using the communication board will be stated for the patient. The board consists of two sides, one side consisting of alphabet and a place for writing, and other side consisting of simple pictures of possible and common patients' needs with subtitle phrases. The communication board is provided to the patient during the morning shift (7 am-1 pm) to communicate with the nurse.

Category

Behavior

2

Description

Control group: In the control group no additional action will be taken. The nurse-patient communication will continue in routine method, like nurse's frequent questions and patient's non-verbally responses and by body movements.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Anahita Divani

Street address

Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran, Iran

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Web page address

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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 Sahraeeian

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Tohid Square, Dr. Mirkhani St. (East Nosrat)

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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

Anahita Divani

Position

masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient privacy

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available