

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of interactive communication application on satisfaction and anxiety of intubated patients admitted to intensive care units

Protocol summary

Study aim

determination of the effect of interactive communication application on satisfaction and anxiety of intubated patients admitted to intensive care units

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: Qom University of Medical Sciences and Health Services

Participants/Inclusion and exclusion criteria

Inclusion criteria: Desire for participating in the study age 18-60 years old Orientation to time, person and place Reading, writing and seeing Ability first experience of hospitalization in Intensive Care unit 24 hours after intubation Exclusion criteria: Hearing, tactile, visual disorders Receiving sedatives, narcotics, benzodiazepines and barbiturates

Intervention groups

Intervention group: After obtaining informed consent and the completion of the Hamilton Anxiety Scale, eligible patients will enter the study immediately after admission in ICU. The desired application will be installed on nurse's mobile phone and the patient will interact via this application with the nurse when the need for communication arises. Control group: After obtaining informed consent and the completion of the Hamilton Anxiety Scale, eligible patients will enter the study immediately after admission in ICU. In the control group the nurse communicates with patient via the routine routes.

Main outcome variables

Satisfaction with communication, Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111203008286N9**

Registration date: **2021-01-05, 1399/10/16**

Registration timing: **prospective**

Last update: **2021-01-05, 1399/10/16**

Update count: **0**

Registration date

2021-01-05, 1399/10/16

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

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of interactive communication application on satisfaction and anxiety of intubated patients admitted to intensive care units

Public title

The effect of interactive communication application on satisfaction and anxiety of intubated patients admitted to intensive care units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Desire for participating in the study age 18-60 years old
Orientation to time, person and place
Reading, writing and seeing Ability first experience of hospitalization in Intensive Care unit 24 hours after intubation

Exclusion criteria:

Hearing, tactile, visual disorders
Receiving sedatives, narcotics, benzodiazepines and barbiturates

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done from the Available samples.
Randomized block with quadruple blocks will be used for division of participants. 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.

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

Designing an application by the researcher that can be installed on mobile phones to facilitate communication of intubated patients hospitalized in intensive care unit

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

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.TUMS.FNM.REC.1399.130

Health conditions studied

1

Description of health condition studied

communication of intubated patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in Hamilton Anxiety Rating Scale(HARS)

Timepoint

Before starting the intervention and 4 days after intervention

Method of measurement

Hamilton Anxiety Rating Scale(HARS)

2

Description

Satisfaction score in Researcher-made questionnaire

Timepoint

Before starting the intervention and 4 days after intervention

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Alert Intubated patients in intensive

care unit that use the application designed by the researcher to communicate with nurses. The target population includes conscious intubated patients admitted to the intensive care units of hospitals affiliated to Qom University of Medical Sciences. The researcher refers to the intensive care units and enrolls patients with inclusion criteria. Sampling will be done from the Available samples. Randomized block with quadruple blocks will be used for division of participants. 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. In the control and intervention group, after obtaining informed consent and completion of HARS questionnaire and researcher-made communication satisfaction questionnaire, eligible patients will be included in the study. In the control group, the nurse will communicate with the patient via the routine communication methods(According to an initial field study in intensive care units affiliated to Qom University of Medical Sciences , the only way to communicate is with the help of yes-no questions and lip-reading) and in the intervention group the desired application will be installed on the nurse's phone and the patient will communicate with the nurse via this application when then need arises. The nurse will use this application every time he/she communicates with the patient and he/she will be required to use this application for the communication during every shift. On fourth day of the study, the mentioned questionnaires will be completed again by the researcher by asking the questions of the questionnaire from the patient without additional explanation about the items. It will be coordinated with the head- nurse how the patients participated in groups will be divided for the nurse so that one nurse does not care for two patients at the same time in the intervention and control groups.

Category

N/A

2

Description

Control group: Alert Intubated patients in intensive care unit that use the routine methods of communication like yes/no question and lip reading, for communicating with nurses

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom University of Medical Sciences and Health Services, Shahid Lavasani St, Qom, Iran

Full name of responsible person

Mohadese Samimi

Street address

No 11, 4th Alley, 31th Alley, Kalhori St, Qom

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3714315511

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silvermoon8916@gmail.com

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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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

Mohadese Samimi

Position

MS student of critical care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Bahramnezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable