Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

City

Qom

Province

Ghoum

Postal code

۳۷۱۴۳۱۵۵۱۱

Phone

+98 25 3723 5849

Email

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

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۵۳۷۶۱

Phone

+98 21 8163 3685

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

Mohadese Samimi

Position

MS student of critical care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

silvermoon8916@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

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

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

Nursing & Midwifery School, East Nosrat st, Tohid sq

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Fax

Email

fatemeh_bahramnezhad@yahoo.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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable